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2005 SEP 16 P 3:14

CCRs APCGen APC/D-D Ritter Burley Heygster

September 16, 2005

BY HAND

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, D.C. 20201

Re: CMS-1501-P--Device Related APCs; (CPT/HCPCS 36516; APC 0112 Apheresis, Selective)

Dear Dr. McClellan:

Kaneka Pharma America LLC ("Kaneka Pharma") is the distributor of the Liposorber® LA-15 System ("Liposorber System"), an innovative Class III medical device providing LDL-apheresis treatment (CPT/HCPCS 36516; APC 0112). For homozygote children and others, ongoing therapy with the Liposorber System to remove low-density lipoprotein cholesterol ("LDL-C") represents a life-saving maintenance therapy. Kaneka Pharma submits these comments in response to CMS's proposed 2006 hospital outpatient prospective payment system ("OPPS") reimbursement for LDL-apheresis treatments. See Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, 70 Fed. Reg. 42674 (July 25, 2005).

As explained below, CMS's payment calculation methodology uses demonstrably inaccurate and unreliable data to calculate a proposed reimbursement amount for APC 0112. Consequently, CMS has proposed an OPPS payment of $1,590.08 that does not cover the basic cost of the disposable devices, other materials and equipment, labor and overhead used in LDL-apheresis treatments. Moreover, the proposed 2006 payment is drastically lower than the current 2005 OPPS rate of $2,127.26. Adoption of the proposed OPPS payment rate potentially would make LDL-apheresis unavailable to the limited but seriously-ill indicated patient population.

Because the data upon which the proposed OPPS payment is based are clearly inaccurate, Kaneka Pharma respectfully requests that CMS reconsider and amend its proposed OPPS rate. Kaneka Pharma requests that: (1) CMS exclude the data associated with CPT 36515

and 36516 from the calculation of the 2006 reimbursement rate for LDL-apheresis[1] and calculate the OPPS rate based solely upon CPT 36522 data, which encompassed the vast majority of claims in APC 0112 in any event;[2] or (2) CMS maintain the 2005 OPPS payment level for APC 0112. Maintenance of the *status quo* under either approach will provide CMS with an opportunity to review and to correct the OPPS rate for APC 0112 based upon accurate cost and claims data.

I. Introduction: LDL Apheresis Provides a Therapy for Desperately Ill Patients.

In 1996, The U.S. Food and Drug Administration ("FDA") approved the Liposorber System for the removal of LDL-C from plasma. Specifically, the Liposorber System is indicated for use to remove LDL-C from the plasma of the following high-risk patient populations for whom diet has been ineffective and maximum drug therapy has either been ineffective or not tolerated: (1) patients with LDL-C $\geq$ 300 mg/dl; or (2) patients with LDL-C $\geq$ 200 mg/dl with documented coronary heart disease. The Liposorber System is comprised of a tubing set, a hollow plasma separator (Sulflux FS-05) and two dextran sulfate LDL-adsorption columns, all of which are disposable and intended for single-use only. Finally, the MA-01, a computer-automated machine, controls the entire Liposorber System. Information describing the Liposorber System is attached as Exhibit A.

The FDA expressly has cited use of the Liposorber System to treat "desperately ill patients." In 1997, the FDA amended its investigational device exemption ("IDE") rules to permit the treatment use of investigational devices in order "to facilitate the availability of promising new therapeutic and diagnostic devices to desperately ill patients...." See 62 Fed. Reg. 48940 (Sept. 18, 1997). The FDA specifically identified the Liposorber System as an example of a device that would have qualified for treatment IDE status:

> Another example of an approved device that would have met the treatment use criteria is the low density lipoprotein (LDL) apheresis system indicated for use in performing low density lipoprotein (LDL) apheresis to acutely remove LDL-C from the plasma of the following high risk patient populations for whom diet has been ineffective or not tolerated....
>
> * * *
>
> This device would have met the treatment IDE criteria because: (1) The device is intended to treat serious conditions, i.e. functional hypercholesterolemic homozygotes with certain LDL-C levels; (2) there are no comparable or satisfactory alternative devices (the only alternative therapies available to treat these high risk patients are diet, which can be ineffective, and maximum drug

[1] Based upon an analysis of the 85 claims in CPT 36515 in 2004, Kaneka Pharma also believes that it would be appropriate to exclude the data for CPT 36515.

[2] The median hospital cost calculated by CMS for CPT 36522 for 2006 is $2,229.37 which is comparable to the 2005 payment of $2,127.26, adjusted for inflation.

> therapy, which can be either ineffective or not tolerated); (3) the device was under investigation in a controlled clinical trial for the same use under an approved IDE; and (4) the sponsor of the controlled clinical trial was pursuing marketing approval of the device with due diligence.

See 62 Fed. Reg. 48940. Thus, the Liposorber System is a unique medical device essential to the well-being of limited but seriously-ill patient populations, particularly young homozygote children.

The proposed 2006 payment for LDL apheresis amounts to a 25 percent reduction from the current 2005 payment. During the annual OPPS rulemaking proceedings, CMS has recognized that fluctuating Medicare reimbursement rates may harm hospitals and, ultimately, Medicare beneficiaries. In last year's rulemaking proceeding, for example, CMS summarized "a number of general public comments" regarding its proposed OPPS 2005 reimbursement rates:

> Some commenters were concerned about the extent to which OPPS payment rates have fluctuated from year to year. Because Medicare payment is a very significant portion of income for most hospitals, they stated that the instability in the OPPS payment rates makes it difficult for hospitals to plan and budget. They indicated that there is a tremendous degree of variation across APCs in terms of payment to cost ratios and that they would expect that after three years of operating the OPPS, the payment to cost ratios would be much more stable.
>
> * * *
>
> Commenters stated that such variation in payments compared to costs puts full-service hospitals and their communities at risk because limited service, or "niche" providers can easily identify and redirect patients with more lucrative APCs to their facilities, leaving full service hospitals with a disproportionate share of patients who receive services that are assigned to the underpaid APCs.

See 69 Fed. Reg. 65687-88 (Nov. 15, 2004).

In response to such comments, CMS "recognize[d] hospitals' need for stability in payments for hospital outpatient services." Id. at 65688. Similarly, in this year's discussion of its proposed payment changes for device-dependent APCs, CMS expressly "recognize[s] that a payment reduction of more than 15 percent from the CY 2005 OPPS to the CY 2006 OPPS may be problematic for hospitals that provide...services" in device-dependent APCs. See 70 Fed. Reg. 42714 (July 25, 2005).[3] As AdvaMed ("AdvaMed") notes in its comments, "continued reductions proposed for CY 2006 will prevent many hospitals from covering their costs, translate into significant losses for hospitals that perform more of these procedures, and lead to access problems for beneficiaries."

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[3] Consistent with CMS's request when it issued the final 2005 payment regulations, Kaneka Pharma submits these comments and accompanying data to assist CMS in "assessing factors that might contribute to instability in...payment rates." 69 Fed. Reg. 65688 (Nov. 15, 2004).

The proposed 25 percent payment reduction for LDL apheresis significantly exceeds the 15 percent reduction recognized by CMS as "problematic" for hospitals in the context of device-dependent APCs. Accordingly, Kaneka Pharma supports AdvaMed's proposal that CMS set a floor on the 2006 device-related APC rates at no less than 100 percent of the 2005 rates for all device-related APCs plus inflation and other update factors.

II. CMS's Methodology and the Data Used To Calculate the Proposed 2006 Payment for LDL Apheresis Are Fundamentally Flawed.

The methodology and data used by CMS to calculate the proposed 2006 payment for LDL apheresis treatment are seriously flawed. Consequently, the application of CMS's payment calculation methodology to such data yielded a proposed 2006 payment which does not cover the basic cost of Liposorber System treatments. Kaneka Pharma outlines these serious methodological and data problems below.

A. The CMS Methodology Used to Calculate OPPS Rates is Unsound.

Kaneka Pharma is a member of the Advanced Medical Technology Association ("AdvaMed"). Kaneka Pharma endorses, and incorporates into these comments, the portions of AdvaMed's submission in this proceeding detailing the methodological deficiencies in the system used by CMS to calculate the proposed 2006 payment rates. More specifically, AdvaMed addresses CMS's heavy reliance on single-procedure claims, use of incorrectly coded claims, and the problems arising from charge compression.

In particular, Kaneka Pharma urges CMS to consider carefully the following recommendations by AdvaMed to improve the accuracy of CMS's payment calculations:

- The mandatory reporting of all device category C codes to facilitate the collection of device cost data;
- The use by CMS of only correctly coded claims for all device-related APCs in setting 2006 reimbursement rates;
- Use by CMS of external cost data when CMS's cost data are inaccurate in order to reflect the cost of device related treatments; and
- Renewed and strengthened efforts by CMS to educate hospitals regarding the importance of accurate coding for devices.

Adoption of these recommendations by CMS would ameliorate many of the problems identified by AdvaMed generally and Kaneka Pharma with respect to APC 0112.

B. The Data Used to Calculate the OPPS Rate for APC 0112 Are Demonstrably Inaccurate and Unreliable.

There are only two providers of approved prescription devices for LDL-apheresis treatment in the United States -- Kaneka Pharma and B. Braun Medical Inc. ("B. Braun"). The FDA required an ongoing patient registry as a post-approval condition of premarket approval for both devices. Because the patient population is limited and the clinical sites, patients and numbers of treatments have been carefully monitored through the patient registry, Kaneka Pharma has complete and accurate data regarding LDL-apheresis treatments using the Liposorber System. Further, Kaneka Pharma has detailed knowledge regarding the cost of its disposable devices to hospitals because it distributes such devices directly to them. Finally, it has consulted with a number of hospitals using the Liposorber System to obtain complete and accurate cost data.

The patient registry information and cost data reviewed by Kaneka Pharma conclusively confirm that the data upon which CMS based its OPPS calculation are grossly inaccurate. As set forth below, such data cannot provide any reasonable basis for OPPS rates. Specifically, the CMS claims data largely do not include the cost of supplies; more than two-thirds of the hospitals reporting LDL-apheresis claims do not perform LDL-apheresis treatments; and many of the reported claims do not involve LDL-apheresis treatments.

(1) Over 75 Percent of Claims for CPT 36516 Did Not Include the Cost of Supplies.

According to the analysis of CMS claims data included in Exhibit B, only 22.9 percent of claims for CPT 36516-0112 included the cost of "supplies." This low reporting rate for supply costs raises serious questions regarding the reliability of the data and appears to have skewed CMS's proposed 2006 payment calculation for LDL apheresis because the Liporsorber System is characterized by high fixed costs.

In addition to its own extensive review of treatment costs, Kaneka Pharma has reviewed LDL-apheresis treatment costs at multiple hospitals, which treat more than 20% of the patients receiving LDL-apheresis therapy with the Liposorber System. Based upon this review, the following chart lists the average cost of supplies associated with Liposorber System treatments.

SUPPLIES	AVERAGE COST (US$)
Disposables	
Liposorber LA-15 Adsorption Column	1,187.50
Liposorber FS-05 Plasma Separator	107.50
Liposorber LT-MA2 tubing sets	55.00
Total	**1,350.00**
Solutions and Anti-coagulant	
1000ml of Lactated Ringer's Injection, USP	8.25
500ml of 5% Sodium Chloride Injection, USP	4.15
1000ml of 0.9% Sodium Chloride Injection, USP	3.43
Heparin Sodium Chloride Injection, USP (30ml)	3.45
Total	**19.27**
Other Materials	
Aspheresis/Dialysis Butterfly Needles	1.90
20ml syringe	1.00
4 x 4 gauze pads	1.37
60ml syringe	0.51
Alcohol prep pads	4.83
Pressure dressing (Coban, ace wrap)	0.77
Tape	0.29
Waste bags (5 liter)	20.19
Gloves, Wipes, etc.	3.00
Total	**33.82**
Equipment Costs	
Apheresis Machine MA-01 / lease fee	63.75
Apheresis Machine MA-01 / maintenance fee	40.31
Total	**104.06**
Labor Costs; Operational Costs	
Nursing Time	218.83
Overhead Fee	621.10
Room Charge	25.00
Total	**864.93**
Total Cost	2,372.08

Thus, the average cost for a Liposorber System treatment amounts to $2,372.08, divided among the following major cost categories:

- $1,350 for the disposable components of the Liposorber System (Liposorber LA-15 Adsorption Column, Liposorber FS-05 Plasma Separator, Liposorber LT-MA2 tubing sets);

- $53.09 for miscellaneous solutions and materials;
- $104.06 for equipment costs (lease and maintenance fees for the MA-01 Apheresis Machine); and
- $864.93 for labor and operational costs (nursing time, overhead expense and room charges).

The reporting of nonexistent or very low costs likely results from erroneous coding by hospital staff, discussed in more detail below. For example, hospital administrative staff may confuse the resources required for LDL-apheresis with the much lower costs associated with plasma exchange (CPT 36514). The relatively low costs associated with plasma exchange treatment include the costs of albumin infusion and simple tubing kits. Notably, plasma exchange treatments are far more common in the United States than LDL-apheresis treatments, which also may account for such mistaken cost allocations.

Regardless of the explanation for the missing supply cost data, the basic cost information compiled by Kaneka Pharma and set forth above illustrates a fundamental defect in CMS's 2006 OPPS methodology. Specifically, the CMS methodology has produced a proposed 2006 reimbursement that falls far below the cost of providing LDL apheresis treatments with the Liposorber System. Kaneka Pharma respectfully requests that CMS keep its stated commitment to "reassess [its] existing methodology each year to determine how [it] can best create rates that uniformly reflect hospitals' cost of providing outpatient services." 69 Fed. Reg. 65751 (Nov. 15, 2004). The proposed 2006 payment for LDL apheresis plainly fails CMS's own test.

(2) Only 30 Percent of the Hospitals With Claims Assigned to CPT 36516 Actually Provide LDL Apheresis Treatments.

As set forth above, LDL-apheresis treatments are performed on a limited patient population and are tracked through a post-approval patient registry. Thus, Kaneka Pharma has comprehensive and accurate information regarding the sites performing LDL-apheresis treatments. Attached as Exhibit C is a list of the 46 hospitals with claims assigned to CPT 36516 according to CMS's claims data.

Based upon Kaneka Pharma's experience as a distributor of the Liposorber System to hospitals and its knowledge of the market for the LDL-apheresis treatments, Kaneka Pharma believes that only 14 of the 46 hospitals listed in Exhibit C potentially provide LDL-apheresis treatments to patients.[4] Specifically, contrary to CMS's claims data, the following hospitals do **not** provide LDL-apheresis treatments:

[4] Kaneka Pharma has determined that 13 of the listed institutions perform LDL-apheresis, utilizing the Liposorber System and/or B. Braun's H.E.L.P. System. Kaneka Pharma has been unable to determine whether one of the institutions (University Community Hospital) performs LDL-apheresis, largely because the name of the institution is ambiguous. In the interest of presenting a conservative analysis, Kaneka Pharma has included this institution in the total of 14 institutions performing LDL-apheresis procedures.

Aultman Hospital (Canton, OH)
Edward W. Sparrow Hospital Association (Lansing, MI)
University of Tennessee Memorial Hospital (Knoxville, TN)
St. Luke's Episcopal Hospital (Houston, TX)
St. Luke's Medical Center (Phoenix, AZ)
Sherman Oaks Hospital and Health Center (Sherman Oaks, CA)
St. Mary's Medical Center (Knoxville, TN)
Norton Hospital/Kosair Children's Hospital/NOR (Louisville, KY)
New England Medical Center Hospital Inc. (Boston, MA)
George Washington University Hospital (Washington, D.C.)
Northeast Medical Center (Concord, NC)
St. Johns Riverside Hospital (Yonkers, NY)
Saint Joseph Hospital & Health Cr Center (Chicago, IL)
Finley Hospital (Dubuque, IA)
Duke University Hospital (Durham, NC)
Brandon Regional Hospital (Brandon, FL)
Good Samaritan Hospital (San Jose, CA)
Mease Hospital Countryside (Safety Harbor, FL)
Fayette Community Hospital (Fayetteville, GA)
Mt. Carmel Health (Columbus, OH)
Fort Sanders Park West Med Center (Knoxville, TN)
Children's Hospital of Alabama (Birmingham, AL)
Hospital of St. Raphael (New Haven, CT)
Chilton Memorial Hospital (Pompton Plains, NJ)
Bethesda Memorial Hospital (Boynton Beach, FL)
Florida Hospital (Orlando, FL)
North Austin Medical Center (Austin, TX)
Pacific Hospital of Long Beach (Long Beach, CA)
Los Robles Regional Medical Center (Thousand Oaks, CA)
Eisenhower Medical Center (Rancho Mirage, CA)
University of California Davis Medical Center (Sacramento, CA)
William Beaumont Hospital (Royal Oak, MI)

Thus, more than two-thirds of the hospitals with CPT 36516 claims do not perform LDL-apheresis treatments under that code.

Such hospitals have incorrectly coded whatever "apheresis" treatments they are performing. Clearly, their cost and charge information necessarily is wrong and irrelevant. Such widespread miscoding seriously undermines the validity of the proposed 2006 reimbursement rate for LDL-apheresis.

(3) Over One Third of the Claims Included in CPT 36516 Do Not Involve LDL-Apheresis.

CMS has assigned CPT 36516 to LDL-apheresis treatment. However, as set forth in Exhibit D, only 40 percent of the 2004 claims used by CMS to calculate the proposed 2006 payment for LDL-apheresis actually refer to LDL-apheresis treatments. In contrast, 15.7 percent of claims refer to treatments for rheumatoid athritis; 13.1 percent of claims refer to treatments for other and unspecified hyperlipidemia; and 5 percent of claims refer to treatments for chronic renal failure. Thus, over one third of the 2004 claims included in the LDL apheresis CPT category simply do not relate to LDL-apheresis treatments.

Erroneous coding by hospital personnel may account for this significant data discrepancy. For example, in preparing CMS documentation for Prosorba treatment for rheumatoid arthritis, hospital personnel mistakenly may have used CPT 36516 (apheresis, selective) for LDL apheresis instead of CPT 36515 (apheresis, adsorp/reinfuse") for Prosorba. Similarly, hospital personnel may have miscoded other and unspecified hyperlipidemia treatments to CPT 36516 rather than CPT 36514 (apheresis, plasma). Finally, coding chronic renal failure treatments to 36516-0112 for LDL apheresis clearly is a mistake given the fundamental difference between dialysis and LDL apheresis treatments.

The following array of similarly denoted CPT codes, all including the term "apheresis" and covering very different apheresis treatments, practically invites mistaken coding by hospital administrative staff:

APC0111 Blood Product Exchange	APC0112 Apheresis, Photopheresis, Plasmapheresis
CPT 36511 for Apheresis wbc	CPT 36515 for Apheresis, adsorb/reinfuse
CPT 36512 for Apheresis rbc	CPT 36516 for Apheresis, selective
CPT 36513 for Apheresis platelets	CPT 36522 for Photopheresis
CPT 36514 for Apheresis plasma	

For example, given the similar nomenclature of those services grouped under APC0111 to those under APC0112, hospital administrative staff erroneously may confuse plasma exchange treatments (CPT 36514) with apheresis treatments under CPT 36516, thereby skewing CMS's payment calculations.

Finally, APC 0112 includes three distinct apheresis treatments: (1) LDL apheresis (CPT/HCPCS 36516); (2) Prosorba (CPT/HCPCS 36515) and (3) Photopheresis (CPT/HCPCS 36522). Each of these therapies uses distinct technologies to treat different disorders. As discussed above and in Exhibit A, LDL-apheresis treats patients suffering from severe hypercholesterolemia. Prosorba is designed for patients with severe rheumatoid arthritis who have not responded to, or are intolerant of, disease modifying anti-rheumatic drugs and patients suffering from idiopathic thrombocytopenic purpura who have platelet counts of less than 100,000 mm. Photopheresis is approved for the palliative treatment of skin manifestations of cutaneous T-cell lymphoma.

CONCLUSION

CMS's flawed methodology and reliance on inaccurate data have produced a proposed 2006 payment for LDL apheresis which does not cover the basic cost of providing the treatment with Kaneka Pharma's Liposorber System. In view of the serious data and methodological flaws, Kaneka Pharma respectfully requests that: (1) CMS exclude the erroneous data for CPT 36515 and 36516 from the calculation of the 2006 reimbursement rate for LDL-apheresis; or, in the alternative, (2) CMS maintain its current 2005 payment for LDL apheresis treatments plus an inflation adjustment factor. Maintaining CMS's current payment for LDL-apheresis will afford CMS an opportunity to review and to address the fundamental errors upon which the proposed 2006 payment is based while continuing to make LDL-apheresis available to the limited, but desperately ill, patient population.

Respectfully submitted,

Kazuo Kuruma

Kazuo Kuruma
President

Enclosures

EXHIBIT B

COST DATA FOR LDL-APHERESIS CLAIMS*

CPT-APC	Total Claims	Percent/Number of Claims with Costs in These Categories			
		Pharmacy	Rooms	Supplies	Lab and Pathology
36516-0112 (apheresis, selective)	502	42.40% / 213	35.20% / 177	22.9% / 114	14.40% / 72

* Data are based upon AdvaMed analysis of CMS claims data.

EXHIBIT C

HOSPITALS WITH CLAIMS ASSIGNED TO CPT-APC 36516-0112

Hospital Name	City	State
New York Hospital	New York	NY
Aultman Hospital	Canton	OH
Hospital of University of Pennsylvania	Philadelphia	PA
Abbott - Northwestern Hospital Inc.	Minneapolis	MN
Hartford Hospital	Hartford	CT
Edward W. Sparrow Hospital Association	Lansing	MI
University of Tennessee Memorial Hospital	Knoxville	TN
St. Lukes Episcopal Hospital	Houston	TX
University of Michigan Health System	Ann Arbor	MI
Cedars-Sinai Medical Center	Los Angeles	CA
Emory University Hospital	Atlanta	GA
St. Luke's Medical Center	Phoenix	AZ
Vanderbilt University Hospital	Nashville	TN
Baptist Memorial Hospital	Memphis	TN
Sherman Oaks Hospital and Health Center	Sherman Oaks	CA
St. Mary's Medical Center	Knoxville	TN
Norton Hospital/Kosair Children's Hospital/NOR	Louisville	KY
New England Medical Center Hospitals Inc.	Boston	MA
George Washington University Hospital	Washington	DC
Northeast Medical Center	Concord	NC
Evanston Northwestern Healthcare	Evanston	IL
St. Johns Riverside Hospital	Yonkers	NY
Saint Joseph Hospital & Health Cr Center	Chicago	IL
Finley Hospital	Dubuque	IA
Maine Medical Center	Portland	ME
Duke University Hospital	Durham	NC
Brandon Regional Hospital	Brandon	FL
Good Samaritan Hospital	San Jose	CA
University Community Hospital	Tampa	FL
Mease Hospital Countryside	Safety Harbor	FL
Fayette Community Hospital	Fayetteville	GA
University of New Mexico Hospital	Albuquerque	NM
Mt. Carmel Health	Columbus	OH
Fort Sanders Park West Medical Center	Knoxville	TN
Childrens Hospital of Alabama	Birmingham	AL
Hospital of St. Raphael	New Haven	CT
Chilton Memorial Hospital	Pompton Plains	NJ
Bethesda Memorial Hospital	Boynton Beach	FL
Florida Hospital	Orlando	FL

North Austin Medical Center	Austin	TX
Pacific Hospital of Long Beach	Long Beach	CA
Los Robles Regional Medical Center	Thousand Oaks	CA
Eisenhower Medical Center	Rancho Mirage	CA
University of California Davis Medical Center	Sacramento	CA
William Beaumont Hospital	Royal Oak	MI

EXHIBIT D

DIAGNOSIS DATA FOR LDL-APHERESIS CLAIMS*

CPT-APC	Total Claims	Percent/Number of Claims By Diagnosis			
		ICD-9 272.0 Pure Hypercholesterolemia	ICD-9 714.0 Rheumatoid Arthritis	ICD-9 272.4 Other and Unspecified Hyperlipidemia	ICD-9 585 Chronic Renal Failure
36516-0112 (apheresis, selective)	502	40% / 201	15.7% / 79	13.1% / 66	5.0% / 25

* Data are based upon AdvaMed analysis of CMS claims data.

170

AMERICAN COLLEGE OF GASTROENTEROLOGY

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September 16, 2005

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Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Hospital Outpatient Prospective Payment System Proposed Rules, July 25, 2005 (CMS-1501-P) Update for Calendar Year 2006, 42 CFR Parts 419 and 485

Dear Dr. McClellan:

The American College of Gastroenterology is pleased to provide these comments on the proposed hospital outpatient payment rule for 2006. We wish to offer comments on the new interpretation of surgical insertion and implantation criterion, the payment level of gastroenterological procedures with stents, and the correction to a payment classification.

INTRODUCTION

The American College of Gastroenterology (ACG) is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers nearly 9,000 physicians among its membership. While the majority of these physicians are gastroenterologists, the College's membership also includes surgeons, pathologists, hepatologists and other specialists in various aspects of the overall treatment of digestive diseases and conditions. The College has chosen to focus its activities on clinical gastroenterology – the issues confronting the gastrointestinal specialist in treatment of their patients. The primary activities of the College have been, and continue to be educational.

Pass-Through Device Categories

Criteria for Establishing New Pass-Through Device Categories – Surgical Insertion and Implantation Criterion

The College was pleased to see the care with which CMS considered comments by ACG and other stakeholders on this issue from the OPPS Final Rule for CY 2005. In addition, we were encouraged to see in the Proposed Rule for CY 2006 that the agency is proposing to consider as eligible for pass-through payments those items inserted or implanted through a natural orifice or surgically created orifice (such as an ostomy). It is disappointing then that the agency intends to address this change merely through a change in interpretation of the existing regulation rather than modifying language in §419.66(b)(3). In not choosing the more concrete method at its disposal, CMS gives the impression of tepid support for this important policy change that benefits patients through increased access to new medical treatment technologies. We hope the agency will instead consider the following language offered by Medtronic in its comments on this proposal:

> §419.66 Transitional Pass-through Payments
>
> *(b)(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is implanted or inserted, through a natural or surgically created orifice or through a surgically created incision, whether or not the device remains with the patient when the patient is released from the hospital.*

Proposed Payment for APC 0384, GI Procedures with Stents

We are concerned that payments for GI stenting procedures, APC 0384, in the proposal are being reduced based on the agency's acceptance of incomplete hospital claims reporting data. As you know, this Boston Scientific brought this concern before the APC Advisory Panel by at CMS on August 18, 2005. The panel agreed with the presentation's findings that the agency's use of claims submitted without corresponding C codes resulting in an under-representation of the true costs associated with performing the procedures under APC 0384. This resulted in median cost differentials of up to almost 300 percent for claims submitted with and without corresponding C codes. A further reduction in payment level for APC 0384 would impede Medicare beneficiary access to these essential stent-based treatment technologies.

Creation of New APC for ERCP Stenting Procedures

Although it was not included in CMS's proposal, the APC Advisory Panel made an additional recommendation regarding two ERCP stenting procedures, CPT 43268 and CPT 43269, included in APC 0384. We respectfully disagree with the panel's recommendation that 1) a new APC needs to be created for these procedures, and 2) that

these two procedures are clinically dissimilar to other procedures in APC 0384. To the contrary, these two procedures actually represent the vast majority of claims in this APC, and are clinically similar via employment of endoscopic and fluoroscopic techniques. When considering the APC panel's recommendation, it is critical to understand that fluoroscopy is fundamental to all gastrointestinal stenting procedures in that the physician cannot visualize the distal stent due to tumor stenosis. Furthermore, x-ray monitoring is required for adequate stent extension across the entire luminal stenosis. Other similarities include that the guidewires used in placing the stents are identical to those used in ERCP and similar equipment and supplies are also used regardless of where a stent is placed within the gastrointestinal tract.

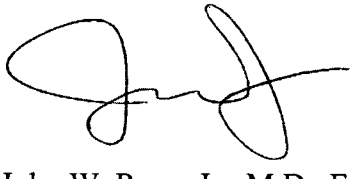
Again, the College urges CMS to calculate the CY 2006 payment median for APC 0384 using only claims that include corresponding C codes, but to reject the APC Advisory Panel's recommendation to create a new APC for CPT 43268 and CPT 43269.

CPT 91035 – *Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation*

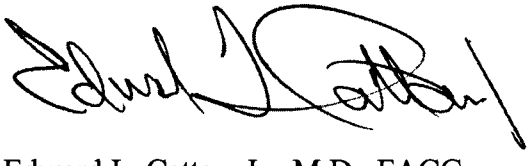
ACG would like to acknowledge the correction notice CMS published in the August 26, 2005, Federal Register that CPT 91035 remain in APC 1506 – *New Technology – Level VI* and not be placed, as was published in the CY Proposed Rule on July 25, 2005, in APC 0361 – *Level II Alimentary Tests*. The agency's prompt corrective action is appreciated.

Thank you for the opportunity to furnish these comments, and please contact us if you have any questions or comments regarding these issues.

Sincerely,



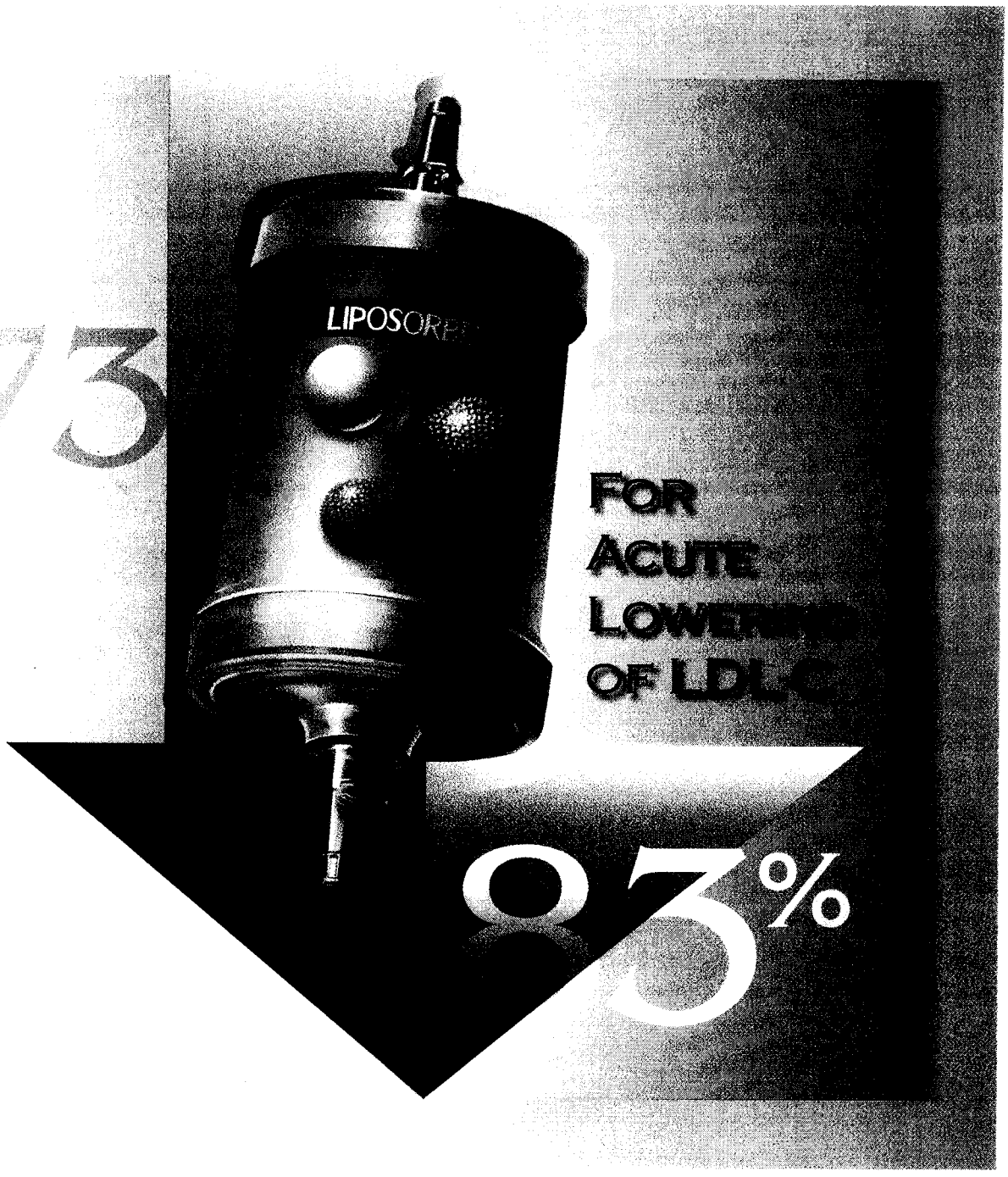
John W. Popp, Jr., M.D., FACG
President, Board of Trustees



Edward L. Cattau, Jr., M.D., FACG
Chairman, National Affairs Committee

BEYOND DIET AND DRUG THERAPY...

LIPOSORBER®



kaneka

The LIPOSORBER LDL Adsorption Column

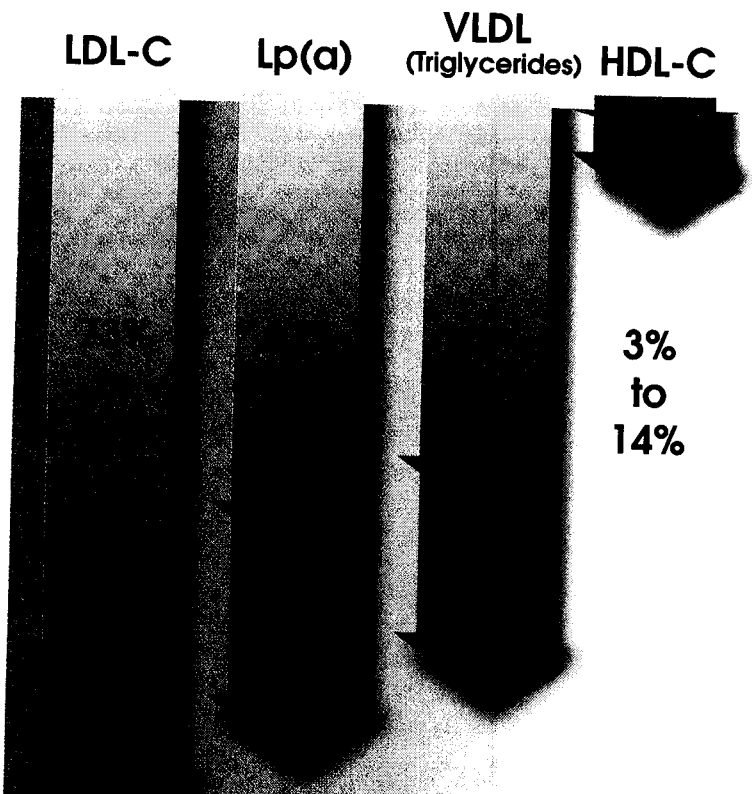
Dextran Sulfate - cellulose beads selectively bind ApoB-containing lipoproteins (LDL, Lp(a) and VLDL). No binding of HDL or other essential plasma components.

Dextran Sulfate - cellulose bead

LDL
Lp(a)
VLDL

HDL

Lowers Lipids In One Treatment



...treatment acutely lowers your ...-C, Lp(a) and triglycerides in ...r treatment, with minimal effect on ...r essential plasma components.

Proven

- Acutely lowers LDL-C 73-83% after a single treatment
- Since 1987, over 250,000 treatments have been performed worldwide

Effective

- Removes ApoB-containing lipoproteins (LDL, Lp(a), VLDL)
- Returns HDL and other essential plasma components back to the patient

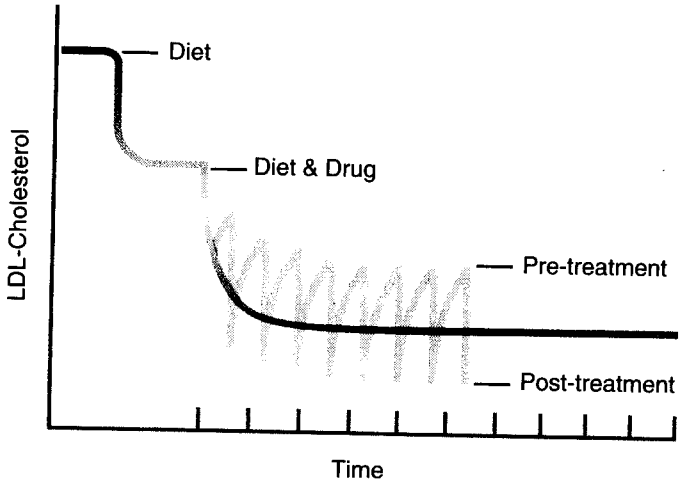
Safe

- Very well tolerated
- No replacement fluids
- No clinically significant changes in laboratory safety parameters with long-term use

Unique

- No other procedure has the flexibility to target a specific LDL-C treatment goal
- Approved for marketing by FDA

LIPOSORBER Treatment Effect on LDL-C



LIPOSORBER treatment, as an adjunct to diet and maximum tolerated drug therapy, dramatically lowers LDL-C more effectively than diet and drug therapy alone.

Indications For Use

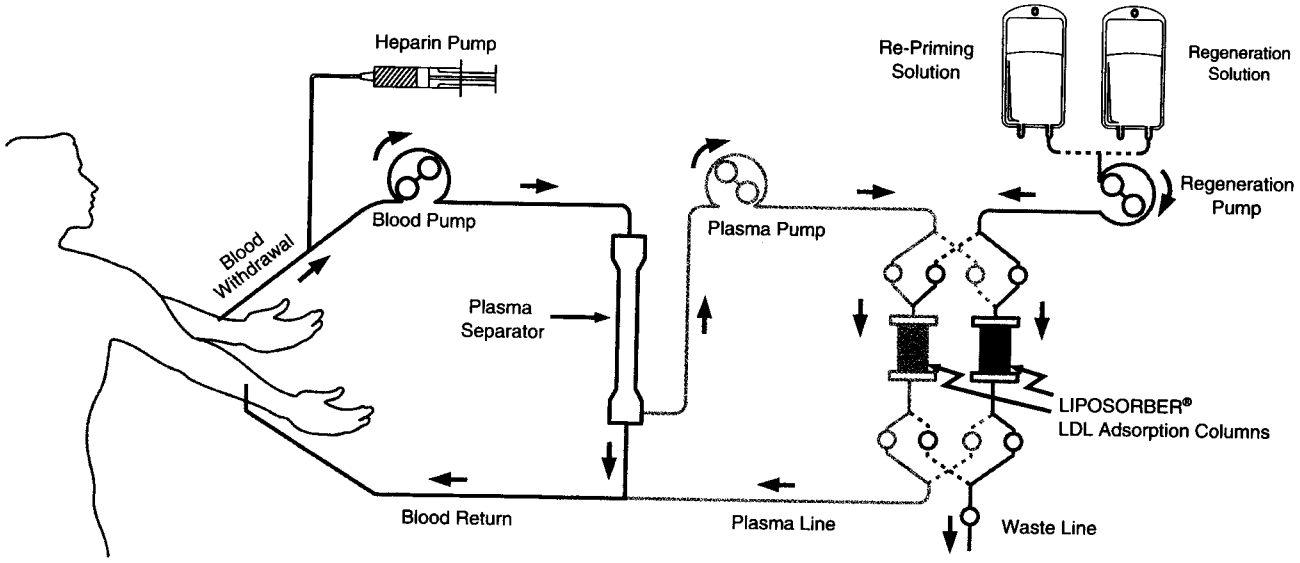
Within a small patient population, a select number of people are candidates for LIPOSORBER treatment. They have not responded adequately to at least six months of diet and maximum tolerated cholesterol-lowering drug therapy. They are patients with:

- LDL-C ≥ 200 mg/dL with documented coronary heart disease (CHD), or
- LDL-C ≥ 300 mg/dL

Treatment Frequency

Patient LDL-C Level	Regimen
200 - 299 mg/dL	Every 2 weeks
≥ 300 mg/dL	Every week

How The LIPOSORBER System Works



1. The patient's blood is withdrawn through a venous access and enters the plasma separator. As blood flows through the hollow fibers of the plasma separator, the plasma is separated and pumped into one of the two LDL adsorption columns. As the plasma passes through the column, the apolipoprotein B-containing lipoproteins - LDL, Lp(a) and VLDL - are selectively adsorbed by the dextran sulfate - cellulose beads within the column. There is minimal effect on other essential plasma components such as HDL-C and albumin.

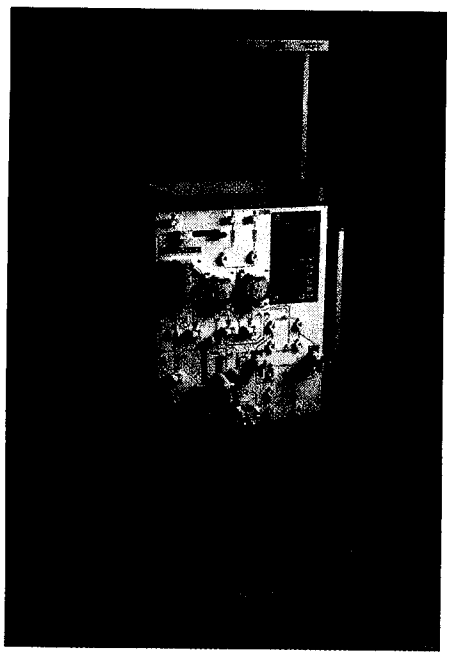
2. The LDL-depleted plasma exits the column and is recombined with the blood cells exiting the separator, after which is returned to the patient through a second venous access.

3. When the first column has completed LDL, the computer-regulated machine switches the plasma flow to the second column.

4. The plasma remaining in the first column is returned to the patient. The column is then regenerated, eluting the LDL, Lp(a) and VLDL that were adsorbed. After elution, the column is regenerated and ready for the next cycle of adsorption. For continuous LIPOSORBER treatment, a complete treatment takes about 2 to 3 hours.

Insurance Companies Have Recognized The Proven Value Of LIPOSORBER Treatment

- LIPOSORBER treatment is considered the **"treatment of choice"** when all other methods have failed to help patients reach their targeted cholesterol goal
- Patients must meet specific criteria before treatment is initiated as outlined in the FDA-mandated patient registry
- The patient registry is overseen by an independent panel of physicians to assure long-term safety and efficacy



Continuous-Flow System

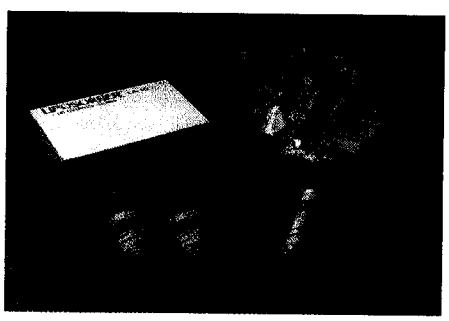
- Eliminates the need for replacement fluid which prevents the possibility of associated complications

Highly Effective

- Removes ApoB-containing lipoproteins (LDL, Lp(a), VLDL) with minimal effect on other essential plasma components such as HDL-C and albumin

Flexible

- Provides you with the ability to target a specific cholesterol treatment goal



Complete

- The LIPOSORBER System includes a disposable tubing set, a plasma separator, two absorption columns, and the LDL-apheresis machine.

For more information visit our website at:

www.liposorber.com

LIPOSORBER®

Kaneka

171

Groupe sanofi aventis
Because health matters

Hugh M. O'NEILL
Vice President

NPT DBR
DA
SCOL

September 16, 2005

BY HAND DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)

Dear Administrator McClellan:

Sanofi-aventis[1] appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed revisions to the Medicare hospital outpatient prospective payment system (HOPPS) regulations (the "Proposed Rule")[2] to implement applicable statutory requirements and certain related provisions of the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA").

Sanofi-aventis is committed to fighting diseases throughout the world. In the new millennium, we have taken up the major challenges of discovering new compounds that are essential to the progress of medical science and launching pharmaceutical products that constitute real therapeutic progress for patients. Our mission is to discover, develop, and make

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1 These comments are submitted on behalf of Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals Inc., members of the sanofi-aventis Group.

2 70 Fed. Reg. 42674 (July 25, 2005).

available to physicians and their patients innovative, effective, well-tolerated, high quality treatments that fulfill vital health care needs.

As a company dedicated to bringing advanced therapies to patients, sanofi-aventis supports the overall goal of the HOPPS to encourage hospital efficiencies and enable hospitals to manage their resources with maximum flexibility. While we generally support the changes presented in the Proposed Rule, we have some comments, questions and recommendations that we hope you will consider. Specifically:

- CMS should provide clarity with regard to the treatment of C-codes after drugs come off of pass-through status.

- We support the use of average sales price (ASP) +6 percent methodology for the reimbursement of drugs and other services, but request clarification regarding what data will be used to establish payment rates as of January 1, 2006.

- We applaud CMS for including administrative and other overhead costs in their payment for services so that hospitals may receive appropriate reimbursement, but recommend CMS spend more time working with hospitals to ensure payment for services accurately reflect such costs.

- We urge CMS to adopt coding and payment for sodium hyaluronate products (hyaluronans/hylans) that is consistent with scientific evidence, equitable to all stakeholders and which will assure patients' access to the specific agent that is most appropriate for their treatment.

- We urge CMS to ensure that hospitals are reimbursed adequately for drug administration services by paying separately for additional infusions and additional hours of infusions and clarifying that hospitals may bill more than one "initial" code per visit.

A more detailed explanation of these comments and concerns, and our specific recommendations for the final rule (the "Final Rule"), are set forth below.

I. Expiration of Pass-Through Status

In the Proposed Rule, CMS itemizes several drugs for which pass-through status will expire on December 31, 2005. Several of these drugs are currently assigned to C-codes. The Proposed Rule does not make clear, however, whether drugs coming off of pass-through status will be reassigned to J-codes or will continue to be listed under their C-code for reimbursement purposes. We request clarification of this matter in the Final Rule.

II. Treatment of NonPass-Through Drugs

A. Data Sources Available for Setting CY 2006 Payment Rates

Section 1833(t)(14)(A)(iii) of the Medicare law directs CMS to set the payment rate for specified covered outpatient drugs in 2006 and beyond so that they are equal to the average acquisition cost for the drug. We support CMS's decision to use ASP+6 percent for separately payable drugs in CY 2006, because we agree that this is the best available means of estimating average acquisition costs for that year. We also support the use of these rates for budget neutrality estimates, impact analysis, and to complete Addenda A and B of the Proposed Rule. For purposes of the Proposed Rule, we support the use of the most recent data that was available at the time it was drafted (i.e., data that was collected during the fourth quarter of 2004).

CMS notes that it will adjust the data in Addenda A and B, which identify payment rates for APCs and individual CPT/HCPCS codes, respectively, using data from the second quarter of 2005 when it publishes the Final Rule. As CMS states, doing so enables it to remain consistent with the ASP-based payments that would be made for drugs administered in physician offices. CMS also states that it will update this data on a quarterly basis during CY 2006. CMS does not make clear in the Proposed Rule, however, precisely what data will be used to establish payment rates as of January 1, 2006.

As CMS is aware, ASP data for the third quarter of 2005 will be available on October 30, 2005. While this will be too late for CMS to use in publishing the Final Rule, we request that this data be used to set payment rates for the first quarter of 2006. Doing so will meet two primary goals of the HOPPS: (1) relying on the most recently available data and (2) remaining consistent with payments made for drugs in physician offices. Addressing this matter directly in the Final Rule will benefit the health care system by adding clarity and predictability as CMS transitions to this new payment methodology.

B. MedPAC Report on APC Payment Rate Adjustment for Specified Covered Outpatient Drugs

As authorized by section 1833(t)(14)(E)(ii) of the Medicare law, CMS announced in the Proposed Rule that it plans to adjust the APC payment rates for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. As reported by MedPAC and stated in the Proposed Rule, handling costs for drugs delivered in the hospital outpatient setting are not insignificant. A recent MedPAC report cites studies that found these costs range from 25-33 percent of pharmacy related direct expenses.[3] We certainly applaud CMS for proposing to pay for overhead costs related to the administration of drugs. However, we recommend that CMS spend more time working with hospital outpatient departments to ensure that the payments accurately reflect the costs of these services.

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[3] Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

In addition, while we believe that reimbursement for these pharmacy and handling services should begin immediately, we support the APC Panel's recommendation that CMS delay implementation of the proposed three C-codes until January 1, 2007. C-codes will help collect better data on these pharmacy costs, but only after they are designed and implemented in ways that recognize the data hospitals are capable of reporting. For example, MedPAC's findings demonstrate that most hospitals do not currently charge for their handling costs and have no systematic, consensus-based approach for measuring such costs.[4] Consequently, more time and effort is needed to develop and refine a methodology for recognizing and recording such costs accurately. Only then will this data collection effort be meaningful.

III. Coding and Payment for Sodium Hyaluronate Products (Hyaluronans/Hylans)

Sodium hyaluronate products are single source products administered by intra-articular injection for the treatment of pain in patients with osteoarthritis of the knee. Currently, there are 5 sodium hyaluronate products (hyaluronans/hylans) approved for commercial use in the US: (1) Hyalgan (Sanofi-Synthelabo, Inc., a member of the sanofi-aventis Group), (2) Nuflexxa (Ferring), (3) Orthovisc (Johnson & Johnson), (4) Supartz (Smith & Nephew) and (5) Synvisc (Genzyme). These products differ in terms of molecular weights, proposed biological effects, active ingredient dose-per treatment, number of treatments-per course[5] and labeling for repeated treatment courses.

Coding for these products has changed frequently over the past several years. In the hospital outpatient setting, currently, there is a single "J" code used to report Hyalgan and Supartz (J7317 "Sodium hyaluronate, per 20 to 25 mg dose for intra-articular injection"), a separate "J" code to report Synvisc (J7320 "Hylan G-F 20, 16 mg, for intra articular injection") and a "C" code to report Orthovisc (C9220 "Sodium hyaluronate per 30 mg dose, for intra-articular injection"). (Nuflexxa is a very recent market entrant, and we are not aware of any specific coding policy for this agent.)

The payment amounts under the Proposed Rule for these agents for a single injection and for the minimum and maximum number of injections per treatment course (according to labeling) are provided in the table below:

Product	Code	Single injection	Minimum course	Maximum course
Hyalgan	J7317	$110.65	$331.95	$553.25
Nuflexxa[6]	??	??	??	??
Orthovisc	C9220	$203.84	$611.52	$815.36
Supartz	J7317	$110.65	$553.25	$553.25
Synvisc	J7320	$203.15	$609.45	$609.45

[4] Id. at 143.

[5] According to package labeling, Hyalgan is given as 3 or 5 injections per course, Orthovisc as 3 or 4 injections per course, Supartz as 5 injections per course and Synvisc as 3 injections per course.

[6] It is unclear whether Nuflexxa will be assigned to one of the established codes for sodium hyaluronate products or will be assigned a unique code.

These proposed payment amounts may create financial incentives for hospitals to stock and use certain products instead of choosing products based on clinical judgment and appropriate treatment for patients.

As we have indicated in meetings with CMS staff as well as at the HCPCS Panel Open Meeting on June 14, 2005, we believe the dosing differences among these agents warrants the creation of specific codes for each single source product. Product-specific coding will allow physicians the flexibility to offer the specific product that in the physician's professional judgment, is most appropriate for an individual patient. We have submitted recommendations to CMS for specific coding and nomenclature that we hope will be adopted for HCPCS 2006.

If our recommendation for specific coding is adopted, we would support CMS assigning specific payments for each product consistent with the methodology for assigning payment for separately payable outpatient drugs under HOPPS as discussed in our comments above.

IV. Coding and Payment for Drug Administration Services

In the Proposed Rule, CMS announces its plans to continue using Current Procedural Terminology® (CPT) codes for drugs administration services.[7] We support this proposal, and we are pleased that, as proposed under the Proposed Rule, CMS will begin using the new, more specific CPT® codes for drug administration in the HOPPS in 2006. These codes were introduced in physician offices this year as part of CMS' implementation of the MMA's requirement to ensure that coding and billing for these services accurately reflects the resources involved.[8] These codes should have a similar effect in the hospital outpatient setting, as well, by allowing CMS to collect detailed charge data that can be used to set more appropriate rates for drug administration services offered in this setting.

Although we support CMS' proposal to use the new codes, we are concerned that the combination of CMS' payment proposed under the Proposed Rule and the codes' guidelines will produce severe cuts in reimbursement for administration services. The coding guidelines for the new codes instruct providers to bill only one "initial" service code when administering multiple infusions, injections, or combinations.[9] For example, when a hospital provides a two-drug chemotherapy regimen, the hospital would code the first chemotherapy drug administered as the "initial" service and the second drug as an "additional" service. Under the Proposed Rule, CMS would pay separately only for the codes categorized as "initial" infusions, but would package payments for all the codes categorized as "additional" services.[10] As a result, the hospital would be paid for administering the first drug, but not the second. Additionally, under the Proposed Rule, CMS would pay for only the first hour of any infusions administered over multiple hours. We estimate that reimbursement for administration of some chemotherapy regimens would be

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[7] 70 Fed. Reg. at 42737.

[8] Social Security Act § 1848(c)(2)(J); 69 Fed. Reg. 66235, 66303 (Nov. 15, 2004).

[9] American Medical Association, CPT 2006, available at http://www.ama-assn.org/ama1/pub/upload/mm/362/cpt2006drugadmin.doc.

[10] 70 Fed. Reg. at 42738-39.

cut under this proposal by as much as 25 percent. Such significant cuts in Medicare payment could harm beneficiary access to care if hospitals determine that they no longer can afford to provide these critical services.

Sanofi-aventis urges CMS to protect beneficiary access to important drugs in hospital outpatient departments by providing adequate reimbursement under the HOPPS for all drug administration services. CMS can achieve this goal by implementing two changes to the Proposed Rule. First, CMS should provide separate payment for additional infusions and additional hours of infusions. We recommend that CMS use its claims data from 2004 and 2005 to set rates for these services in 2006. Second, CMS should instruct hospitals to ignore the coding guidelines regarding billing of "initial" services. These changes will simplify hospitals' coding efforts and will help ensure that hospitals continue to provide advanced drug therapies in their outpatient departments.

V. Conclusion

In closing, sanofi-aventis supports the goals of the HOPPS and largely agrees with the steps CMS has proposed to update the system.

We appreciate this opportunity to raise our questions and concerns about the Proposed Rule, and we look forward to working with CMS to implement changes to the HOPPS in a manner that optimizes efficiency and reduces costs, while enabling hospitals to engage in medical practices that lead to healthier patients and minimize morbidity and mortality. We hope our suggestions will help CMS address these important issues in the Final Rule. Please contact me if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

Hugh O'Neill
Vice President, Integrated Healthcare Markets

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172

NCQDIS

September 14, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates [CMS-1501-P]

The National Coalition for Quality Diagnostic Imaging Services (NCQDIS) respectfully submits these comments in response to the proposed rule on the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates as issued by the Centers for Medicare and Medicaid Services ("CMS") in the Federal Register on July 25, 2005.

NCQDIS is comprised of more than 2,400 outpatient imaging centers and departments in the United States. The coalition promotes "best industry practices," strategies for healthcare cost savings and advocates for public and private sector standards for quality and safety in diagnostic imaging services. Advances in diagnostic imaging have led to great strides in patient care: from reducing the need for invasive surgical procedures to early detection of life-threatening diseases. NCQDIS and its members are at the forefront of medical technology, providing physicians and patients with the most state-of-the-art innovations, techniques and procedures available in diagnostic imaging.

We applaud CMS for its commitment to providing Medicare beneficiaries with quality health care; however, we are very concerned that CMS has failed to include improvements to quality for diagnostic imaging services in its proposed rule. We are concerned that CMS has focused on only one aspect of diagnostic imaging services provided to Medicare beneficiaries—specifically, cutting payments for imaging services provided to contiguous body parts. CMS has not addressed the broader quality and utilization issues, which have a more compelling impact on quality of care provided to Medicare beneficiaries and on preserving scarce Medicare trust fund dollars. NCQDIS urges CMS to evaluate these important issues before implementing any policy changes for diagnostic imaging services. NCQDIS respectfully recommends that CMS delay implementation of these proposed payment changes, until CMS fully evaluates all of the quality and utilization issues in diagnostic imaging. NCQDIS submits that CMS should only implement its proposed coding edits/payment changes if these changes are part of a broader, comprehensive reform package that adequately addresses quality of care concerns and the overutilization of diagnostic imaging services within the Medicare program.

Multiple Diagnostic Imaging Procedures

Under the current Outpatient Prospective Payment System (OPPS), hospitals receive full payments for multiple diagnostic imaging procedures conducted in a single day regardless of whether contiguous areas of the body are studied in the same session. CMS has proposed a 50%

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reduction in (1) the technical component and (2) the OPPS payment for some second and subsequent imaging procedures performed in the same session.

CMS noted in the proposed rule that codes within particular families of services are often provided during the same session to obtain the clinical information necessary to diagnose and treat a patient. While each procedure by itself utilizes a certain amount of hospital resources, some of those resource costs are not incurred twice when the procedures are performed in the same session. Therefore, the multiple imaging procedure reduction will apply only when more than one service within a family are performed in the same session. CMS proposes to make the full payment for the procedure with the highest APC rate and payment at 50% of the applicable APC rate for every additional procedure performed that session.

NCQDIS supports coding edits only as part of a broader package of reforms to promote appropriate utilization of diagnostic imaging services. In its March 2005 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) recommended that the Secretary improve Medicare's coding edits that detect unbundled and mutually exclusive services and reduce the technical component payment for multiple diagnostic imaging services performed on contiguous body parts on the same day. MedPAC also made several additional recommendations, in addition to updating coding systems, that were designed to further improve the quality of diagnostic imaging services and improve utilization of these procedures. NCQDIS believes that coding edits/payment changes should only be implemented, if CMS also implements the other MedPAC recommendations:

1. The Secretary should use Medicare claims data to measure fee-for-service physicians resource use and share results with physicians confidentially to educate them about how they compare with aggregated peer performance. The Congress should direct the Secretary to perform this function.

2. The Congress should direct the Secretary to set standards for all providers who bill Medicare for performing diagnostic imaging services. The Secretary should select private organizations to administer the standards.

3. The Congress should direct the Secretary to set standards for physicians who bill Medicare for interpreting diagnostic imaging studies. The Secretary should select private organizations to administer the standards.

4. The Secretary should expand the definition of physician ownership in the Ethics in Patient Referrals Act to include interest in an entity that derives a substantial proportion of its revenue from a provider of designated health services.

NCQDIS agrees that additional steps must be taken to ensure that Medicare beneficiaries have access to the best quality care provided by the best-trained specialists. Reducing reimbursements for scans of contiguous body parts does not address these broader issues of quality and utilization of diagnostic imaging services in Medicare—these problems will still exist even if CMS implements its proposed cuts to payments for contiguous body parts.

The proposed changes to coding/payment should only be considered if other reforms are also implemented. Imaging equipment and facilities operated by providers not specifically trained to provide complex diagnostic imaging services are often sub-optimal with regard to equipment quality, technicians operating the equipment, the quality of images produced, and ultimately interpretation of these diagnostic images. Appropriate training is a particularly important, as an unbiased interpretation of an image by a physician trained to interpret all areas of the body is the best way to prevent misdiagnosis. In addition, the use of aging equipment and images taken by improperly trained technicians inevitably produces a low-quality image that even the best-trained physician will have trouble interpreting.

NCQDIS recommends implementation of a comprehensive reform package that will improve the quality of patient care and protect Medicare trust fund dollars. Implementation of the coding edit system alone does not address the issues of quality and overutilization – Medicare has cut costs for certain services, yet potential quality problems and overutilization still exist. NCQDIS addresses these issues through broad-based reform, paralleling those implemented under the Mammography Quality Standards Act (MQSA), that will do the following:

#1) Redefine Medicare Coverage for Complex Diagnostic Imaging: Institute education and quality standards requirements for Medicare coverage and payment of complex diagnostic imaging services, inluding MRI, CT, and PET. Current coverage and payment requirements would continue for cardiac ultrasound procedures, plain X-rays, and other non-complex services.

#2) Implement Quality Standards: Require all providers of diagnostic imaging services to meet safety and quality standards, including:

- Education standards
- Standards for staff qualifications and quality monitoring procedures
- Quality standards for radiographic and other images
- Quality standards for facilities, particularly maintenance, safety and routine inspection of equipment to limit use of aging equipment
- Quality procedures and record keeping for non-radiologists analogous to radiologists

#3) Update Coding Systems: Require CMS update billing systems to more accurately reflect changes in technology

In Phase II of NCQDIS' reform proposal, CMS would expand quality standards to additional diagnostic imaging services through a demonstration program after quality standards for complex diagnostic imaging services have been successfully put in place.

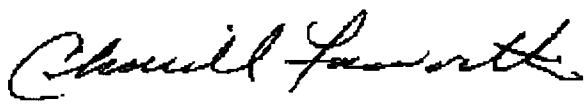
Conclusion

Medicare patients deserve to receive care from health care providers that are adequately trained to perform imaging services and use well-maintained imaging equipment that meets defined quality standards. The proposed changes in the rule regarding contiguous body parts are only one potential method of managing Medicare resources, and should only be implemented within

the context of larger reform efforts that address diagnostic imaging quality and utilization concerns.

NCQDIS appreciates this opportunity to submit comments to CMS regarding its Proposed Rule on the Hospital Outpatient Prospective Payment System, and we look forward to working with CMS as on this and other issues affecting diagnostic imaging services. If you have any questions about these comments, please feel free to contact me at 281-447-7000.

Sincerely,



Cherrill Farnsworth
Chairperson, NCQDIS

173

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We are smith&nephew

Wednesday, September 14, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
445–G Hubert H. Humphrey Building
200 Independence Avenue, Southwest
Washington, DC 20201

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates [CMS-1501-P] – Non Pass-Throughs

Dear Dr. McClellan:

Smith & Nephew is a global medical technology leader specializing in the development of advanced, cost-effective medical treatments. In particular, Smith & Nephew specializes in cutting-edge therapies for advanced wound management, endoscopy and orthopaedics.

Smith & Nephew is committed to the development of innovative and lifesaving medical technologies, and the company welcomes CMS' similar commitment to Medicare beneficiaries nationwide.

Smith & Nephew respectfully submits these comments to request correction of the erroneous product classification and reimbursement rate proposed for DERMAGRAFT® in the Hospital Outpatient Prospective Payment System [HOPPS]. DERMAGRAFT [C 9201/J 7342] is a human fibroblast-derived dermal substitute used to treat diabetic foot ulcers. The apparent problem rests in how CMS is calculating the reimbursement for bioengineered, living human tissue products. The proposed rule sets the reimbursement for bioengineered, living human tissue products at a rate reflecting the mean costs derived from 2004 hospital claims data rather than as a "specified covered outpatient drug" at a rate of ASP plus six percent. The result of this payment change is a significant and inappropriate decrease in reimbursement that could jeopardize access to this important advance in chronic wound therapy.

Medicare Beneficiaries, the Incidence of Diabetes and Diabetic Foot Ulcers

First, it is very important to understand the importance of this product in successfully treating diabetic foot ulcers and the significance for the Medicare population, both for clinical and economic reasons. According to the American Diabetes Association, 18.2 million Americans [6.3 percent of the population] suffer from diabetes. In 2002, direct and indirect expenditures attributable to diabetes were estimated at

$132 billion. Direct medical expenditures alone totaled $91.8 billion: $23.2 billion for diabetes care, $24.6 billion for chronic complications associated with diabetes, and $44.1 billion for excess prevalence of general medical conditions.[1]

Diabetic foot ulcers affect approximately 15 percent of all diabetics at some point during their lifetime.[2] The average diabetic foot ulcer episode can last several months and in some cases years. Lingering diabetic foot ulcers significantly increase medical expenditures. Costs of ulcer care have been estimated in the range of $4,595 per ulcer to nearly $28,000 for the two years after diagnosis.[3] The majority of diabetic foot ulcers are treated in the hospital outpatient setting, but severe ulcers can result in extended hospitalization. Research has found that the length of stay of diabetes patients listing a foot ulcer condition is 59 percent longer than for diabetes patients without ulcers.[4]

In addition, diabetic foot ulcers can often lead to more serious medical problems, including lower extremity amputations and increased mortality rates. The longer an ulcer persists, the greater the possibility that the patient will develop a serious infection that may lead to hospitalization and possible amputation. Diabetic lower-extremity ulcers are estimated to be responsible for 92,000 amputations every year.[5] The CDC reported in 2003 that approximately 60 percent of all lower extremity amputations occur among people that suffer from diabetes, and of those amputations, approximately 85 percent are preceded by a foot ulcer.[6] Within five years of a person's first lower extremity amputation, 28 – 51 percent of patients with diabetes require a second leg amputation[7], and the five-year survival rate after a lower extremity is 27 percent.[8] Total costs for diabetic foot disease in the United States, which include ulcer care and amputations, approach $6 billion annually.[9]

The cost of diabetic and other lower-extremity ulcers is particularly problematic for the Medicare program. In 2002, 20 percent of non-institutionalized Medicare beneficiaries were living with diabetes.[10] In 1995, over 400,000 Medicare beneficiaries, 7.3 percent of diabetic beneficiaries, had lower-extremity ulcers.

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[1] "Economic Costs of Diabetes," American Diabetes Association, *Diabetes Care* 26:917-932 [2003].
[2] Diabetes in America, 2nd Edition, National Institute of Diabetes and Digestive and Kidney Diseases, NIH Publication No 95-1468 [1995].
[3] "Incidence, Outcomes, and Cost of Foot Ulcers in Patients with Diabetes," Ramsey, S.D., et. al, *Diabetes Care* 22:382-387 [1999]; "Costs and Duration of Care for Lower Extremity Ulcers in Patients with Diabetes," Holzer, S.E.S. et. al, *Clin. Therapy.* 20:169-181 [1998].
[4] Diabetes in America, 2nd Edition, National Institute of Diabetes and Digestive and Kidney Diseases, NIH Publication No 95-1468 [1995].
[5] "A Cost Analysis of Diabetic Lower-Extremity Ulcers," Harrington, Catherine, et. al, *Diabetes Care* 23:1333-1337 [2000].
[6] "History of Foot Ulcer Among Persons With Diabetes, United States, 2000 to 2002," CDC,
[7] "A Cost Analysis of Diabetic Lower-Extremity Ulcers," Harrington, Catherine, et. al, *Diabetes Care* 23:1333-1337, [2000].
[8] "A Cost Analysis of Diabetic Lower-Extremity Ulcers," Harrington, Catherine, et. al, *Diabetes Care* 23:1333-1337, [2000].
[9] Diabetes in America, 2nd Edition, National Institute of Diabetes and Digestive and Kidney Diseases, NIH Publication No 95-1468 [1995].
[10] "Medicare Chart Book, Third Edition," The Henry J. Kaiser Family Foundation [2005].

A study released by the Lewin Group revealed that Medicare spent $1.45 billion in 1995 on lower extremity ulcer-related treatment. The study also found that Medicare expenditures per year for lower-extremity ulcer patients were $15,309 in 1995, compared to $5,226 for other Medicare patients – this is a 300 percent increase in Medicare cost from the average Medicare patient. In light of its findings, the Lewin report concluded that, "any wound care intervention that could prevent even a small percentage of wounds from progressing to the stage at which inpatient care is required may have a favorable cost affect on the Medicare system."

DERMAGRAFT® – Human Fibroblast-Derived Dermal Substitute

As noted above, DERMAGRAFT [C 9201/J 7342] is a human fibroblast-derived dermal substitute used to treat diabetic foot ulcers. The fibroblasts, seeded onto a bioabsorbable mesh material produce collagen, proteins, growth factors and cytokines – in essence, using active, living cells to replace damaged tissue in chronic ulcers. DERMAGRAFT is placed directly on the wound, and the fibroblasts are gradually absorbed to promote healing. DERMAGRAFT is FDA indicated for use in the treatment of full-thickness diabetic foot ulcers greater than six weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure.

DERMAGRAFT has become an important treatment option for patients suffering from diabetic ulcers, as treatment with DERMAGRAFT results in faster wound healing and better patient outcomes. In clinical studies, patients treated with DERMAGRAFT were 1.7 times more likely to heal than the control group. In a recent study, patients experienced a 79 percent reduction in average time to 50 percent wound closure compared to the standard treatment group. After 12 weeks, 71 percent of ulcers healed when treated with DERMAGRAFT versus 14 percent of the control group. In another study, after week 12, the median percent wound closure was 91 percent among patients treated with DERMAGRAFT compared to 78 percent in the control group. Most importantly, there were virtually no reoccurring ulcers on healed DERMAGRAFT-treated ulcers after 42 months.

DERMAGRAFT Coding and Reimbursement

DERMAGRAFT was first reimbursed in the hospital outpatient setting with pass-through status as a device in 2000. In 2001, CMS changed the status of the product from a device to a biologic, stating that DERMAGRAFT was not eligible for pass-through status as a device because it was not surgically implanted or inserted into the patient. In 2001, Smith & Nephew submitted a biologic pass-through application. Since 2002, CMS has treated DERMAGRAFT as a biologic for reimbursement purposes:

Dates	Medicare Reimbursement Rate
April 1, 2002	DERMAGRAFT® acquired pass-through status as a biologic.
2002 - 2004	Reimbursed as a biologic at 95 percent AWP.
2004 to date	With passage of the Medicare Modernization Act [MMA], DERMAGRAFT was reimbursed as sole source biological in 2004 and 2005 under the "specified covered outpatient drug" provision.

Notably, the MMA defines a "specified covered outpatient drug" [SCOD] as a drug or biologic that [1] has a separate APC, and [2] is a biological for which payment was made on a pass-through basis on or before December 31, 2002. By this definition, DERMAGRAFT is clearly a "specified covered outpatient drug" under the statute because it [1] has a separate APC [9201], and [2] payment was made on a pass-through basis in April 2002, well before the December 31, 2002 deadline.

In the Notice of Proposed Rulemaking [NPRM] for the Hospital Outpatient Prospective Payment System rates for 2006, CMS proposes to reimburse DERMAGRAFT and other bioengineered, living human tissue products at a rate reflecting the mean costs derived from historical 2004 hospital claims data rather than as a "specified covered outpatient drug" at a rate of ASP plus six percent.

The result of this NPRM is a significant and inappropriate decrease in reimbursement. The proposed reimbursement rate under the NPRM is only $368.32 for 2006. This proposed reimbursement rate is well below the ASP reported quarterly to CMS for DERMAGRAFT. By way of reference, the most recent ASP for DERMAGRAFT reported to CMS was $548.66. Another bioengineered living tissue product, Apligraf [C 1305/J 7340], also faces a significant decrease, with a proposed reimbursement rate of $766.84 in 2006 as compared to $1,130.88 in 2005.

The result of this error is a significant decrease in Medicare reimbursement for DERMAGRAFT that will critically hinder patient access to this treatment. The new reimbursement rate is completely out of line with the product's current reimbursement rate and the actual cost of the product.

A study released by the Government Accountability Office on June 30, 2005, estimated DERMAGRAFT's average sales price [ASP] to be $545.10, based on its survey methodology. In 2004, DERMAGRAFT was reimbursed at a rate of $535.04, and in 2005, DERMAGRAFT is being reimbursed at a rate of $529.54. The proposed reimbursement rate under the NPRM is only $368.32 for 2006 – this represents a 30 percent decrease in reimbursement from 2005.

The proposed 2006 payment will not adequately reimburse providers for DERMAGRAFT, forcing providers to choose to rely on less effective, traditional therapies or use the more effective wound treatment at a significant financial loss. Providers will therefore limit use of the product, threatening the availability of this treatment option and possibly compromise the health of numerous Medicare beneficiaries.

The decrease in patient access to DERMAGRAFT® and other bioengineered, living human tissue products will have serious consequences for Medicare beneficiaries. Without access to DERMAGRAFT and other bioengineered, living human tissue products, Medicare patients that suffer from diabetic ulcers will have to rely on less effective conventional treatments and therapies. As noted above, conventional therapies often lead to longer healing times, increasing patient risk of infection and amputation. By creating disincentives to using more effective bioengineered, living human tissue products, Medicare is inadvertently increasing the likelihood of increased hospital stays, amputations, and other complications attributed to diabetic ulcers.

This drastic change in reimbursement rate will have a significant affect on patient access and product availability. It will make it extremely difficult for Smith & Nephew and other medical technology innovators to produce advanced technologies. Bioengineered, living human tissue products represent a crucial treatment option for patients suffering from chronic ulcers – Medicare should not implement a payment policy jeopardizing the availability of this important advanced wound-healing technology. As such, the proposed rule should be corrected to align with the agency's previous determinations that DERMAGRAFT is a "specified covered outpatient drug" and as such should be appropriately reimbursed at ASP plus six percent. On this latter point, Smith & Nephew strongly supports payment parity at levels set by ASP plus six percent for this product regardless of whether it is applied in the physician office setting or in the hospital outpatient setting.

Smith & Nephew appreciates this opportunity to submit comments to CMS regarding its 2006 Proposed Rule on the Hospital Outpatient Prospective Payment System. If you have any questions about these comments, please feel free to contact me at 202.626.8235.

Best regards,

Mary E. Hayter

Mary E. Hayter
Vice President, Government Affairs

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WELLSTAR
Health System

Wound Treatment Center

September 12, 2005

Mark B. McClellen, M.D., PhD
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
Attn: CMS – 1505 – P
P. O. Box 8016
7500 Security Boulevard
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

File Code: CMS – 1505 – P
Proposed Payments for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

Dear Dr. McClellen:

As a practicing physician treating patients with chronic wounds, I am very concerned with the proposed 2006 Medicare Hospital Outpatient payment for Dermagraft [C 9201] and Apligraf [C 1305].

For this reason, I am submitting comments in response to the Centers for Medicare and Medicaid Services [CMS] Proposed Rule - Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule.

Apligraf and Dermagraft are distinctive living human tissue substitutes for the treatment of chronic wounds. These products have improved the quality of life of thousands of diabetics and Medicare beneficiaries who suffer from chronic wounds. Many of these patients would have had to undergo amputations without the benefits of Dermagraft and Apligraf.

Practicing physicians, like me, treating a variety of chronic wounds have been able to use these living tissue substitutes to successfully treat Medicare beneficiaries when other treatment modalities have been unable to heal these difficult wounds.

As you may know, since 2002 both Apligraf and Dermagraft were paid as biologics under the Hospital Outpatient transitional pass through program. Both products also have been paid for as sole-source biologics in 2004 and 2005 with the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

In the proposed 2006 Medicare Hospital Outpatient Rule, CMS plans to reimburse covered outpatient drugs at average sales price [ASP] + six percent for the acquisition cost of the drug.

For some reason however, in the proposed rule both Apligraf and Dermagraft were incorrectly paid based on 2004 claims data instead of payment based on ASP. Because of the claims data calculation, both products experienced a significant decrease in payment which is unacceptable for purchasing hospitals:

Dermagraft **2005 hospital outpatient payment = $ 529.54**
2006 proposed hospital outpatient payment = $ 368.32

Apligraf **2005 hospital outpatient payment = $ 1,130.88**
2006 proposed hospital outpatient payment = $ 766.84

Dermagraft and Apligraf have been reimbursed in the hospital outpatient setting as covered outpatient drugs and this payment methodology should continue in 2006 like other covered outpatient drugs. Without this, Medicare beneficiary access to these advance treatment options is jeopardized by the payment rates in the 2006 Medicare proposed rule.

I request that the proposed 2006 Medicare hospital outpatient reimbursement for Apligraf and Dermagraft be corrected in the final rule that will be issued later this year

Thank you for your prompt attention and correction of this 2006 payment issue.

Best regards,

Lisa A Oakley, M.D.

174-1

WELLSTAR Health System

Wound Treatment Center

September 12, 2005

Mark B. McClellen, M.D., PhD
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
Attn: CMS – 1505 – P
P. O. Box 8016
7500 Security Boulevard
Baltimore, MD 21244-8018

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DA KANE
E/M Stamm Hunter

September 15, 2005

The Honorable Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)

Dear Administrator McClellan:

On behalf of the Oncology Nursing Society (ONS) – the largest professional oncology group in the United States composed of more than 33,000 nurses and other health professionals who are dedicated to ensuring and advancing access to quality care for all individuals affected by cancer – we appreciate this opportunity to submit formal comments to the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS). As part of its mission, the Society stands ready to work with policymakers at the local, state, and federal levels to advance policies and programs that will reduce and prevent suffering from cancer, including initiatives that seek to ensure adequate reimbursement for cancer-related care paid for by the Medicare program and other public and private payors.

ONS would like to commend CMS for a number of recent payment policy changes to the OPPS and thank the agency for its efforts to implement the MMA in a timely and straightforward manner. While CMS has made modifications to payment rates and associated policies that help strengthen the provision of oncology care in hospital outpatient departments, ONS does have concerns that other Medicare payment policies could result in diminished access to – and quality of – care for Medicare beneficiaries with cancer.

Given the role that oncology nurses play in the provision of quality cancer care through chemotherapy administration and associated supportive care in all cancer care settings, our comments will highlight issues of principal concern to oncology nurses treating patients in hospital outpatient departments. With respect to modifications to particular payment rates and other policies for hospital outpatient-based cancer care drugs and services, we urge CMS to give full consideration to the detailed comments submitted by other key stakeholders from the oncology community, particularly the Association of Community Cancer Centers (ACCC). ONS thanks CMS in advance for its consideration of our recommendations outlined below and those submitted by the ACCC.

Oncology Nurses Play an Integral Role in the Provision of Community-Based Cancer Care

The provision of quality cancer care requires a multidisciplinary team of professionals, including physicians, nurses, social workers, pharmacists, nutrition counselors, and laboratory technicians. Oncology nurses are on the front-lines of the provision of quality cancer care and each day they utilize very specialized skills to coordinate and administer the comprehensive, high quality cancer treatment and supportive care Medicare beneficiaries need and deserve. Specifically, oncology nurses play an essential role in administering chemotherapy, managing patient therapies and side-effects, stabilizing patients during an emergency, documenting important information in patient charts, working with Medicare and other payors to ensure that patients receive the appropriate treatment, providing counseling to patients and family members, triaging patient questions and problems during the day, as well as during non-business hours, in addition to many other daily acts on behalf of people with cancer. ONS maintains that all treatment and supportive care – provided by oncology nurses, oncology social workers, and other members of the interdisciplinary cancer care team – should be covered and reimbursed adequately by the Medicare program.

Adequately Reimburse for Drug Administration and All Associated Nursing Time

ONS supports CMS' proposal to begin using the new drug administration CPT® codes in the OPPS in 2006. We believe the new codes, providing more detailed descriptions of drug administration services than the old codes, will help CMS collect the data it needs to establish more adequate payment rates in the future. We are concerned, however, that the 2006 proposed rates for these services will not prove adequate to cover hospitals' costs of delivering drug therapies, particularly for those patients who receive multiple infusions during a single visit or whose infusions take more than one hour to administer. Many patients receive therapies that indeed take longer than one hour to be delivered and many of those patients, as well as others, often receive more than one infused therapy on a given treatment day.

The safe, effective delivery of chemotherapy requires the skills and knowledge of a highly trained, well-educated oncology nurse who can employ state-of-the art understanding of cancer care. To that end, the time that nurses spend administering drugs to cancer patients in hospital outpatient departments involves myriad activities, including but not limited to: closely monitoring patients' vital signs, responding to any urgent or emergent situations, adjusting and/or ceasing therapies as necessary, continuously assessing the IV site for patency, checking for blood return, watching for pain, burning, stinging, redness, or swelling, etc. All of the assessment, planning, interventional, and evaluative services and expertise provided by oncology nurses to their patients – particularly during an infusion – require significant time, effort, and focus and as such, ONS believes warrant adequate Medicare payment and recognition in its coding and payment system.

Given the role of nurses in chemotherapy and supportive care drug administration, ONS maintains that Medicare should provide adequate reimbursement for the entire time it takes for

the preparation and administration of chemotherapy and any supportive care drugs (including hydration) to each individual patient. To that end, ONS urges CMS to modify 2006 payments and coding as necessary to ensure that all of the nursing time employed to provide chemotherapy and supportive care in the hospital outpatient setting is reimbursed and that all individual infusions and drug administrations for an individual patient during a single visit are paid adequately.

Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy

As we have previously commented to the agency, ONS appreciates that the 2005 Physician Fee Schedule included a one-year demonstration project to "assess and provide new support for the quality of care for patients undergoing chemotherapy." The quality-of-care and quality-of-life for people with cancer has been a long-standing ONS concern and the Society seeks to work with CMS and other stakeholders to ensure that patient outcomes are maximized.

ONS welcomes the opportunity to work with CMS and other stakeholders to expand the demonstration to include patients being treated in hospital outpatient departments, should the "demonstration project" be extended in 2006. We will discuss our recommendations for the future of this study of quality cancer care for Medicare beneficiaries in our comments on the proposed physician fee schedule rule which we will be submitting to CMS later this month. However, in the interim, we would like to note that ONS feels strongly that no Medicare beneficiary – irrespective of the care setting in which they are being treated – should be required to pay coinsurance or co-payment or otherwise have to bear any additional costs associated with their "participation" in a study created to evaluate the quality-of-care they are receiving.

Evaluation and Management (E/M) Services

Supportive care services for people with cancer are essential components to oncology care and cannot – nor should not – be decoupled from the provision of chemotherapy, radiation oncology, and other modes of anti-cancer treatment. Supportive care – most often provided by oncology nurses and other non-physician health professionals – often is under-reimbursed, or not reimbursed at all, in both hospital and physician office settings. Posing a further challenge to hospitals securing adequate reimbursement for these essential services is that many are not clear as to how they are to code and bill for them. As we have commented previously, evaluation and management (E/M) codes could – and should – include important cancer care support services such as, nutritional assessment and counseling, psychosocial counseling, chemotherapy teaching.*

* Chemotherapy teaching typically is a one hour educational visit to the oncology care setting spent one-on-one with the oncology nurse discussing the course of treatment, explaining possible chemotherapy side effects, reviewing how to manage such side effects, learning how to recognize serious problems, answering patient and family questions, etc.

It is our understanding that CMS has not yet issued coding guidelines for E/M services provided during clinic visits. As such, ONS urges CMS to adopt the AHA/AHIMA expert panel recommendations for a national set of coding guidelines for hospital clinic visits, including visits for cancer care support services, so as to provide much-needed clarification and guidance to hospitals as to how to code and bill for oncology supportive care services. Doing so will help ensure that hospital outpatient departments receive the reimbursement they deserve for providing quality, comprehensive care to Medicare beneficiaries with cancer and help preserve the ability of hospital outpatient departments to provide ambulatory cancer care. Without such support, some hospital outpatient departments could cease providing cancer care – or face reducing the provision of much-needed services and care – and people with cancer could be forced to receive care in the inpatient setting, which is more expensive, not as accessible, and less convenient for patients.

Summary

ONS believes the adoption of the aforementioned recommendations and those being submitted by the ACCC will help ensure that hospital outpatient departments are able to provide quality, comprehensive cancer care to all Medicare beneficiaries in need. However, without such action, there is the possibility – particularly in rural and other underserved areas, where many patients do not have ready access to cancer treatment in the physician office setting - that access to comprehensive cancer care could be compromised. Oftentimes, a hospital outpatient cancer center is the sole provider of ambulatory cancer care in a community or is the only appropriate setting for certain therapies (e.g. radiopharmaceuticals) to be delivered. ONS advocates that clinical decisions with regard to the best course and type of treatment – and appropriate care delivery setting – should be made by health care providers together with their patients and should not be dictated or otherwise influenced by payment practices or policies. We urge CMS to take action to ensure access to care in hospital outpatient departments – a setting that is an integral part of our nation's cancer care infrastructure.

Please know that we stand ready to work with you and your colleagues to develop and implement Medicare payment policy changes that provide adequate and appropriate payment for the full range of cancer-related care, ensure access to comprehensive quality cancer care for seniors with cancer, and prove fiscally responsible for the nation. Should you or your staff have any questions, please contact us, or our ONS Health Policy Associate in Washington, DC, Ilisa Halpern (202/230-5145, ihalpern@gcd.com). Thank you again for your consideration of our views.

Respectfully submitted,

Karen Stanley, RN, MSN, AOCN®, FAAN
President

Pearl Moore, RN, MN, FAAN
Chief Executive Officer

176

PROBITAS PHARMA

Scientia et ethica pro salute

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September 16, 2005

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Via Electronic Mail
Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1501-P
Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule entitled "Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" (hereinafter, the OPPS Proposed Rule). CMS is to be lauded for its consistent use of market-based payment methodologies across both the physician office and hospital outpatient clinic sites of service. Market-based reimbursement rates such as average sales price (ASP) offer many advantages over other methodologies. However, without careful attention to the potential impact of changing payment methodologies unintended consequences can and do arise. As described more fully below, Grifols is concerned that the proposed OPPS rates for intravenous immune globulin (IVIG) may have devastating consequences for the patients who rely on this life-saving therapy.

Grifols is a major producer of plasma therapies including hemophilia blood clotting factors, IVIG, and human serum albumin. While we are concerned generally with the adequacy of the OPPS proposed payment rates, our comments relate primarily to IVIG. This is because from among those therapies we produce, IVIG is most often administered in the outpatient setting.

Introduction

As outlined more fully below, we are concerned that the proposed ASP +8% payment rate for IVIG will have the unintended consequence of hindering access to care for the critically ill patient populations who rely on it. While we applaud the use of ASP as a benchmark, we believe the add-on payment of 8% will not be adequate to cover the product acquisition and pharmacy overhead costs associated with IVIG. To avoid this outcome, we propose that CMS establish an interim 2006 payment rate based on either:

- the outcome of Lewin Group study of hospital acquisition and pharmacy overhead costs associated with IVIG, or
- a dampening mechanism that would reduce the payment for IVIG not more than 15% for 2006.

We recommend that either of these short term measures be implemented pending the outcome of a more comprehensive and independent study of hospital acquisition and pharmacy overhead costs being conducted by the Lewin Group. The results of this more comprehensive study can serve as the basis for establishing an appropriate and evidence-based add-on payment for IVIG.

Further, we request that CMS act immediately to establish separate healthcare common procedure coding system (HCPCS) codes for each branded and unique IVIG preparation. This will help assure that access to all brands of IVIG is preserved. Access to all brands of IVIG is critical to the patient populations served by this life saving therapy because the unique biological attributes of one therapy may confer clinical benefits not provided by another brand.

These recommendations are intended to be consistent with the comments and recommendations submitted by other stakeholders including the Plasma Protein Therapeutics Association (PPTA) and various consumer/patient organizations, IVIG manufacturers, distributors and group purchasing organizations. A more detailed discussion of these recommendations and proposals follows.

Background

As a healthcare company committed to producing life-saving therapies like IVIG, Grifols is primarily concerned with assuring patient access to the products we produce. Assuring access to care means ensuring that all brands of therapy are available at all sites of service. Reimbursement policies can unwittingly have the effect of shifting patients from one site of service to another more costly site of service or clinically less appropriate therapy. Equally important, reimbursement policies can have a direct impact on the economic health of a niche bio-pharmaceutical industry like the plasma fractionation industry.

As noted above, our recommendations concerning the 2006 OPPS payment rate for IVIG principally pertain to the ASP add-on payment amount currently proposed at 8%. It is important to note that any increase in the add-on payment for IVIG will not increase the manufacturers' revenues. Rather, an increase in the add-on amount will help to assure that all brands of therapy are available at all sites of service. Increasing the add-on payment will serve to help assure that clinics and treatment centers can adequately cover the costs associated with the obtaining and administering IVIG. This is a critical factor to sustaining the overall health and viability of the plasma fractionation industry.

As CMS payment rates for IVIG decline, it becomes less financially feasible for providers to obtain and administer IVIG. This has the impact of driving down demand for the therapy. As demand for IVIG falls, the already fragile economic environment of the plasma fractionation industry becomes even more challenging. Ultimately, if the economic health of the plasma fractionation industry is not maintained, there will be fewer producers, fewer product choices, and less access to needed therapy.

A clear example of circumstance is the vaccines industry which suffered under economic conditions similar to those of the plasma industry. Today, as I am sure you are aware, there are chronic shortages of needed vaccines. Last year, a national health crisis occurred after the FDA-mandated shut down of the only US supplier of the influenza vaccine. Thousands of vulnerable populations went without their needed vaccinations.

Similarly, over the past three years the plasma fractionation industry has undergone a period of significant economic adversity. Three major producers of IVIG have exited the plasma market as a result of unfavorable economic pressures: Aventis Behring, Alpha Therapeutic Corporation, and Bayer Biologicals. More recently, the American Red Cross has announced plans to exit the plasma therapies market by the end of 2005. Although there have been some new entrants to the US market, such as Grifols, it is clear that the economics of plasma fractionation are challenging and that the companies producing plasma therapies are vulnerable to seemingly minor supply and demand trends. These supply and demand trends are often linked to reimbursement methodology. Consequently, we request that CMS carefully consider the potential impact of the proposed 2006 OPPS rates for IVIG.

ASP Add-On Payment for IVIG

Grifols applauds the use of average sales price as a benchmark for setting 2006 OPPS rates for IVIG. However, we remain concerned that the proposed add-on payment of 8% will be inadequate to cover the hospital acquisition and pharmacy overhead costs. If this is the case, outpatient clinics may not be able to afford the acquisition, stocking, inventory management and administration costs incident to IVIG treatment.

As CMS is surely aware, the switch to ASP+6% in the physician office setting under Medicare Part B has significantly disrupted the routine treatment of patients receiving IVIG in that site of service. As has been reported in the news media and elsewhere, many physicians have stopped administering IVIG in the office setting and instead have referred patients to hospital clinics. Now, as CMS considers establishing an add-on payment for IVIG in the hospital outpatient clinic setting, the same risk is present.

If access to this site of service is impaired as a result of inadequate reimbursement, patients may have to resort to the inpatient setting for their IVIG infusions. Not only is the inpatient setting much more costly, the very real possibility of infection transmission makes the hospital potentially dangerous for patients who may already suffer with compromised immune systems. In order to avoid this unintended consequence, we have provided short term and long term recommendations for setting an appropriate IVIG add-on payment to ASP.

Short Term Solutions

Through its trade association, the PPTA, Grifols is helping to fund an independent study of hospital acquisition and pharmacy overhead costs for IVIG. This pilot study is being performed by the Lewin Group; neither Grifols nor any PPTA member company will direct its outcome or results. Grifols believes that as a short term solution, the results of this study should be used as "proxy rate" for the ASP add-on for IVIG.

We appreciate CMS' concurrence with the MedPAC study finding that the handling costs associated with biologics are "not insignificant". Further, CMS' has appropriately acknowledged that the payment rate for covered biologicals must cover both the product acquisition cost and the pharmacy overhead costs. These conclusions have led CMS to increasing the ASP add-on payment from 6% to 8%. While this 2% increase to the add-on payment will help off-set some of the hospital costs, we are concerned that it may not go far enough. Consequently, we recommend that CMS look to the results of the Lewin Group pilot study to set a proxy rate for the 2006 OPPS add-on payment to ASP.

Alternatively, we recommend that CMS employ a dampening provision similar to that used in 2003 when many products lost their pass-through status and were paid under the median cost methodology. Like 2003, the shift in payment methodology proposed for 2006 would drastically reduce the payment rate for IVIG. For example, at present the payment rate for IVIG in the hospital outpatient setting is $80.68 (83% of average wholesale price (AWP)). The proposed 2006 OPPS payment rate for liquid IVIG of ASP+8% would be $56.71. (This is based on the current Medicare Part B rate of ASP+6% for liquid IVIG at $55.93.) Thus, even accounting for a 2% increase in the ASP add-on to cover pharmacy overhead costs, the proposed payment for IVIG is a reduction of 30%.

It is unreasonable to expect hospital outpatient clinics to be able to adjust to such a drastic reduction in payment without significant consequences. These consequences are most likely to take the form of clinics deciding not to acquire, stock and administer IVIG therapy. This will be tantamount to denying access to care for the patients who rely on IVIG and may well lead to adverse health consequences among this vulnerable population.

Consequently, we recommend that CMS adopt a dampening provision that will limit the reduction in payment rate for IVIG to 15% during the first year of the new payment methodology. A maximum 15% payment reduction for IVIG will force cost efficiencies among hospital outpatient clinics but will not likely lead to a compromise in patient care. This could be achieved by setting the add-on payment at a level equal to the dollar amount necessary to achieve a payment reduction of no more than 15%. In this way CMS can continue to use the market-based ASP as a reimbursement benchmark and can do so in a manner that will optimize patient care and healthcare costs.

Long Term Solutions

In order to assure long-term uninterrupted access to IVIG in the hospital outpatient setting, a comprehensive study of hospital acquisition and pharmacy overhead costs is needed. Like the pilot study briefly described above, a comprehensive study of this nature is perhaps the only way to assure that hospitals are provided adequate payment. Although a product specific study of this nature may be impracticable for large volume sales pharmaceuticals, the relatively small market for IVIG use is amenable to such a study. Grifols, in conjunction with our industry trade association and other IVIG producers, is funding just such a study.

Just as we recommend that CMS adopt as an interim measure a proxy rate for the ASP add-on for IVIG based on a pilot study being conducted by the Lewin Group, we also recommend that CMS consider adjusting the ASP add-on for IVIG once the results of a comprehensive Lewin Group study of hospital acquisition and pharmacy overhead costs is complete. It is regrettable that the results of the comprehensive study will not be available in time to be considered for the 2006 rate setting process. However, in light of the fact that the ASP rates will be adjusted quarterly, we recommend that CMS also consider changes to the ASP add-on with this same periodicity. Of course, any change in the add-on payment would need to be based on credible data and information. We anticipate that the comprehensive Lewin Group study will produce this type of credible data and information.

It is worth noting again, that neither Grifols, PPTA nor any other company lending financial support to the Lewin Group studies will direct the study outcome or results. Furthermore, the entire study methodology will be available to CMS for review and analysis. A more complete description of the study is attached to these comments.

Separate HCPCS Coding for Branded IVIG Therapies

As noted above, Grifols applauds CMS for the use of ASP as a benchmark for payment rate setting. However, the current practice of including more than one branded IVIG preparation under a single HCPCS code will contribute to ongoing

access to care problems. This is the result of the fact that the calculation of ASP across different branded therapies results in a payment rate that is below many of the products within that HCPCS code. Further, the bundling of multiple branded therapies within a single HCPCS code makes all products in the class vulnerable to anomalous market circumstances.

On December 15, 2004 Grifols submitted a request for a separate HCPCS code for our proprietary IVIG preparation, Flebogamma 5%. The basis for this request was the unique formulation of Flebogamma 5%. Unlike other IVIG preparations, Flebogamma 5% is produced using sorbitol as a stabilizer rather than glucose, sucrose or maltose. As a result, Flebogamma 5% has a risk profile different from other IVIG preparations with respect to the incidence of renal failure, stroke and myocardial infarction. Grifols also presented its case for a separate HCPCS code at the June 14, 2005 HCPCS public meeting. We are still awaiting the CMS response to our request.

The selection of stabilizer in the production of IVIG is just one of many factors that dictate the unique biochemical profile of each branded IVIG preparation. Other characteristics that impact product tolerability include: volume load, osmolarlity, IgA content, and pH. Depending on the patient's individual health profile, one or more of these product characteristics may determine which product is most clinically appropriate. Thus, one patient may have an adverse reaction to a product that another patient tolerates perfectly well. Consequently, the process of selecting the appropriate product is often one of trial and error. Because of this unique patient and product matching, it is important that access to all products be maintained.

Establishing separate HCPCS codes based on national drug code (NDC) numbers will help maintain access to all brands of therapy because it would assure that the ASP benchmark is appropriate for each product. Under the current bundling schema where multiple therapies are included in a single HCPCS code, the published ASP is too low to cover the acquisition costs of many of the products included in that code. As a result, affordability becomes an access limiting factor and ultimately can contribute to suboptimal clinical care.

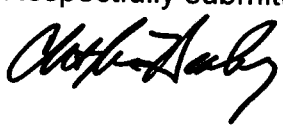
CMS already has acknowledged that important distinctions exist among IVIG preparations. On March 18, 2005 CMS published Medicare Claims Processing Transmittal 507 which created separate "Q codes" for liquid and lyophilized IVIG preparations. While the distinction between liquid and lyophilized IVIG preparations is an important factor in terms of convenience and ease of preparation, it is clinically less significant than the chemical properties listed above. Consequently, we request that CMS consider these more clinically significant factors and establish separate HCPCS codes for each branded IVIG therapy.

Conclusion

Based on the foregoing, we respectfully request that CMS consider short term measures to bolster the add-on payment for IVIG under the proposed OPPS payment rate of ASP +8%. These short term measures may include either the adoption of a proxy rate derived from a preliminary Lewin Group study of hospital acquisition and pharmacy overhead costs or the establishment of a dampening provision to maintain the payment reduction for IVIG to not greater than 15%. As a longer term measure aimed at sustaining access to this life-saving therapy, we recommend that CMS consider data from a comprehensive Lewin Group study of hospital acquisition and pharmacy overhead costs as soon as such data are available. In addition, we urge CMS to establish separate HCPCS codes for each branded IVIG therapy on the basis of their unique biochemical and clinical attributes as well as the public health benefits that would attach from and NDC based HCPCS schema for IVIG.

Thank you once again for the opportunity to comment on the proposed rule for the 2006 OPPS payment rates. If you have any questions about these comments or the information contained herein, please feel free to contact me.

Respectfully submitted,



Christopher Healey
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177

Roche

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2005 SEP 16 P 3:02

September 16, 2005

BY HAND DELIVERY

Mark McClellan, Administrator
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200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)

Dear Administrator McClellan:

Hoffmann-La Roche Inc. ("Roche") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") proposed revisions to the Medicare hospital outpatient prospective payment system ("HOPPS") to implement applicable statutory requirements and certain related provisions of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (the "Proposed Rule").[1]

As a company dedicated to bringing advanced therapies to patients, Roche supports the overall goal of the HOPPS to encourage and enable hospitals to manage their resources with maximum efficiency and flexibility while assuring beneficiary access to innovative health care. While we generally agree with a number of the changes presented in the Proposed Rule, we would request that you consider the following specific recommendations:

- Consistent with previous policies, CMS should continue awarding pass-through payment status to qualified new drugs,[2] which provides incentives in reimbursement to encourage adoption of new innovative drugs.

- The $50 threshold set by the MMA for designating separately payable drugs in the HOPPS setting in 2006 should be extended for future years. However, to the extent that CMS seeks to modify this threshold, it should establish a reasonable price index inflating factor.

[1] 70 Fed. Reg. 42674 (July 25, 2005).
[2] We will use the term "drugs" to refer to both drugs and biologicals throughout this comment.

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Roche

- CMS should utilize the most recent available data in calculating average sales price (ASP) and update the corresponding payment rates on a quarterly basis. Quarterly lags are feasible timeframes for data collection and the issuance of guidance to hospitals.

- Hospital pharmacy overhead costs should be reflected in the reimbursement rates for the administration of all separately payable drugs.

- APC payment rates for separately payable drugs should reflect the actual handling costs for the administration of the drugs within each category - as closely as available data will permit. We recommend that CMS utilize the June 2005 MedPAC Report to the Congress to further inform the establishment of drug handling-fees.

- New drugs that have not yet obtained a HCPCS code should continue to be reimbursed at 95% of its average wholesale price (AWP).

- Equitable Adjustment authority should not be applied in the future for single-source drugs.

A more detailed explanation of these comments and concerns, and our recommendations for the Final Rule, are set forth below.

Pass-Through

We are disappointed by CMS' decision to implement an average sales price ("ASP") methodology to pay for drugs with pass-through status. This proposal reduces the benefits to new drugs and negates the intent of the pass-through payment, which was meant to compensate hospitals for costs not covered by APC payments. Given the long-standing history of the Balanced Budget Refinement Act, the MMA, and Congress' efforts to reward innovation in the development of drugs and biologics, CMS' decision to replicate the reimbursement methodology for current drugs represents a fundamental shift in how it views new drugs entering the marketplace. We urge CMS to consider maintaining a differential in payment systems between innovative and older drugs in order to ensure adequate access for newer therapies within the hospital outpatient setting.

Non Pass-Through

Proposed Criteria for Packaging Payment for Drugs

We support the further development of the APC system as vital to the goals of the HOPPS. Accordingly, it is important to recognize, as CMS does in the Proposed Rule, that packaging payments for certain drugs may result in insufficient payment to hospitals, which could adversely affect beneficiary access to medically necessary services.

To this end, the Act permits the establishment of separate APCs for drugs that cost more than $50 per administration in CYs 2005 and 2006.[3] We support the current $50 threshold

[3] Section 1833(t)(16)(B) of the SSA.

exception. To the extent that CMS may elect to raise the threshold in CY 2007 and beyond, we suggest that it be linked to an appropriate price indexing mechanism. In establishing the appropriate price indexing measure, we urge CMS to give substantial weight to the impact caused by capturing more high-cost drugs in packaged payment groups, including the effect it may have on beneficiary access to needed treatments with particular focus on avoiding unintended disadvantages for newer innovative products.

Data Sources Available for Setting CY 2006 Payment Rates

Section 1833(t)(14)(A)(iii) of the Act directs CMS to set the payment rate for specified covered outpatient drugs in 2006 and beyond so they are equal to the average acquisition cost for the drug. We support CMS's decision to use ASP+6 percent for specified covered outpatient drugs in CY 2006, because we agree that this is the best available means of estimating average acquisition costs for that year. We also support the use of these rates for budget neutrality estimates and impact analysis. Moreover, so long as these payment rates are updated on a quarterly basis, hospital reimbursement rates should accurately reflect acquisition costs.

MedPAC Report on APC Payment Rate Adjustment for Specified Covered Outpatient Drugs

As authorized by section 1833(t)(14)(E)(ii) of the Act, CMS announced in the Proposed Rule that it plans to adjust the APC payment rates for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Based upon MedPAC analysis, handling costs for drugs delivered in the hospital outpatient setting are not insignificant. We urge CMS to reconsider the findings of MedPAC, which found handling costs in the range of 26 – 50% of acquisition cost of drugs and provide appropriate compensation to hospitals for their drug handling costs. In addition, CMS should ensure that the add-on payment is applied equally to all drugs, including those on pass-through and new to the market.

We also support the development of three distinct APC codes for drug handling categories and the collection of this data over the next two years for use in establishing payment rates based on actual costs in CY 2008 and beyond. Payments for these new categories should be based on a weighted average of the overhead costs for all drugs to which the categories will apply, thus ensuring the most accurate payment level possible while meeting the objective of the proposal to streamline the overhead payment system.

HCPCS Codes

Roche supports CMS's proposal to pay for new drugs prior to the assignment of a HCPCS code at an amount equal to 95 percent of the drug's AWP. Doing so will enable hospitals to bill and receive payment for a new drug immediately upon a drug's approval by the FDA. As stated in the Proposed Rule, AWP should correspond to the payment rate established by Fiscal Intermediaries using the *Red Book* or an equivalent recognized compendium.

Roche

Equitable Adjustment

We support CMS' decision not to continue applying an equitable adjustment standard to erythropoiesis stimulating agents (ESAs) available in the hospital outpatient setting. In light of the Agency's determination to move toward an ASP-based system, it would be particularly inappropriate to continue utilizing this price referencing tool.

If CMS elects to utilize the ASP system in the hospital outpatient department setting, it should not abandon one of the central tenets of ASP--reimbursing single source drugs under a single source payment methodology. When enacting the MMA, Congress made a conscious decision to limit the number of exceptions to the single-source payment rules. Congress believed that single-source drugs and biologics approved by the FDA should be treated fundamentally different than multi-source drugs. If CMS wishes to further the policy goals of an ASP based system, it must apply the intent of the law consistently in all settings. Thus, we respectfully suggest that CMS reaffirm that it will no longer equitably adjust reimbursement for erythropoiesis stimulating agents.

Conclusion

Roche appreciates this opportunity to submit comments on this Proposed Rule. We hope our suggestions will help CMS address important beneficiary access issues in the Final Rule.

Thank you for your attention to this important matter. Please feel free to contact me if you have any questions or need any additional information.

Respectfully submitted,

Michael J. Eging
Executive Director
Public Policy and Federal Government Affairs

178

APC/ Our Body KYPHON

September 15, 2005

Mark McClellan, M.D., Ph.D.
Administrator
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Department of Health and Human Services
Rm. 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1501-P
Proposed Changes to the Hospital Outpatient Prospective Payment System: Recommend APC Assignment of Kyphoplasty to APC 0681 or APC 0425

Dear Administrator McClellan:

On behalf of Kyphon, Inc. (Kyphon), we are pleased to submit comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule: Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2006 (70 Fed. Reg. 42,674). Kyphon is the leading manufacturer of innovative medical devices used for "kyphoplasty" procedures to restore spinal function and treat vertebral compression fractures. For elderly Medicare patients, kyphoplasty is an important treatment which reduces pain, restores mobility and function, and helps patients to regain a high quality of life. For this reason, we support Dr. Michael Marks' recommendations for new APC assignments for kyphoplasty procedures.

Kyphon believes that appropriate hospital outpatient payment for kyphoplasty is important to ensure that patients have access to kyphoplasty procedures in all practice settings. We have been supportive of our hospital customers and physicians in their efforts to ensure appropriate reimbursement for kyphoplasty. For 2005, we understand that CMS "temporarily" assigned the C-codes for kyphoplasty to an APC using charge data for *vertebroplasty* as a reference point with a minor adjustment for "incremental" costs for kyphoplasty. However, we understand that AMA CPT Panel has established new Level I CPT codes for kyphoplasty, effective January 1, 2006. These new codes "bundle" the bone biopsy procedure together with the kyphoplasty procedure (unlike vertebroplasty). Consequently, physicians and hospital outpatient departments will no longer be able to bill and be paid separately for the biopsy procedures.

For these reasons, we support Dr. Marks' recommendations that CMS examine the charge data and reassign kyphoplasty procedures to a clinically similar APC that is more closely aligned with the resources used such as APC 681 Knee Arthroplasty ($8,103) or APC 425 Level II Arthroplasty with prosthesis ($5,920). We agree that these APCs would better reflect the clinical features and resources that are needed for kyphoplasty procedures. In addition, movement to a new APC would be supported by the data showing average and median charges exceeding $16,000 which has been submitted by hospitals across the country.

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KYPHON

In closing, we are supportive of our hospital customers and, therefore, we feel it is important to advocate on their behalf as well as the Medicare patients that will benefit from access to kyphoplasty procedures in the hospital outpatient setting.

We appreciate the opportunity to submit these comments and we are pleased to assist and provide any additional information that CMS may find helpful in moving forward to implement these changes. Please feel free to contact me or our reimbursement counsel, Gail Daubert, at 202.414.9241, if we can provide further information.

Sincerely,

Mary Hailey

Mary Hailey,
Vice-President Health Care Policy
Kyphon Inc.

cc: Don Thompson, CMS
Edith Hambrick, M.D., J.D., CMS
Carol Bazell, M.D. CMS
Michael Marks, M.D., Norwalk Hospital
Richard Mott, Kyphon Inc.

179

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APC D-D Heyqster
NOT APC Hunter
Spolter
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September 16, 2005

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Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: **CMS -1501-P** Medicare Program; Proposed Changes to the Hospital Outpatient PPS for Calendar Year 2006: Device-Related APCs, Prosthetic Urology – APCs 163, 385 and 386, Inpatient Only List, and New Technology

Dear Dr. McClellan:

American Medical Systems ("AMS") is pleased to submit comments in response to the July 25, 2005 Proposed Rule ("Proposed Rule") on Changes to the Medicare Hospital Outpatient Prospective Payment System ("OPPS") and Calendar Year 2006 Payment Rates (70 Fed. Reg. 42,674).

AMS is a leader in medical devices and procedures to treat urological and gynecological disorders such as erectile dysfunction ("ED"), urinary incontinence, and menorrhagia. Although not life-threatening, these disorders can greatly affect one's quality of life and social relationships. As such, AMS is keenly interested in the changes recommended in the Proposed Rule concerning payment rates for prosthetic urology devices and procedures. Our comments are intended to ensure that OPPS payment for these devices and services supports high quality care for Medicare patients.

AMS is also a member of the Coalition for the Advancement of Prosthetic Urology ("CAPU"). CAPU is a national organization that includes leading clinical experts and researchers in prosthetic urology. AMS supports CAPU's comments on the proposed OPPS rule for 2006 and wishes to emphasize the following points.

Our recommendations are summarized briefly below:

- Reassign CPT code 52282 *Cysto with insertion of urethral stent* to APC 429 Level V Cystourethroscopy or APC 385 Prosthetic Urology. CPT code 52282 cystoscopy with insertion of urethral stent is currently assigned in APC 0163 but it is neither clinically similar to the other procedures in this group, nor similar in terms of hospital resources. The clinical and resource features of CPT 52282 are more appropriately classified to APC 429. Alternately, CPT code 52282 should be reassigned back to APC 385 (where it was assigned in 2004) to maintain the clinical homogeneity and resource similarity required by the APC system.

- Reassign CPT code 0084T *Insertion of temporary prostatic urethral stent* to APC 429 with CPT 52282 or assign this procedure to APC 385 Prosthetic Urology.

- Remove the proposed AMA CPT Code requirements for New Technology APC applications.

- Change status indicator from "C" to "T" for CPT codes 57282 and 57283 and assign these procedures to APC 202.

- Payment adjustments for Device-Related APCs subject to proposed reductions. We support proposals to appropriately capture device and technology costs. However, at this point, we object to setting floors with increases for the basket update for a selective group of device-related APCs that have received preferential treatment under HOPPS for the past several years, namely the APCs for Neurostimulators, and Cardiac Defibrillators. AMS and others have repeatedly noted that the payment rates for prosthetic urology (APCs 385 and 386) fall short of covering hospital costs and despite the APC Advisory Panel's recommendations to use external data to appropriately adjust the payment rates, CMS has declined to do so. At the same time, CMS has used external data to increase payment for neurostimulators and cardiac defibrillators. At some point, hospitals need to be responsible for submitting appropriate claims. For this reason, we are opposed to special payment concessions or increases for a select group of APCs that has routinely already received preferential treatment under the HOPPS, especially when these increases will likely lower the payment rates for prosthetic urology.

- Payment for device-dependent APCs 385 and 386.
  Appropriate payment for prosthetic urology procedures is critical to ensure that Medicare beneficiaries have access to these important therapies. HOPPS payment for prosthetic urology has been inadequate under the OPPS for the past several years and while the proposed payment rates project an increase for 2006, the rates, if finalized, would still fall short of adequate reimbursement for hospitals.

I. APC Reassignment Needed for Urethral Stent Procedures (CPT 52282 and 0084T) To Ensure Clinical and Resource Similarity of APCs Urethral Stents are Better Aligned with Procedures in APC 429

CPT code 52282 is currently assigned to APC 0163 but it is neither clinically similar to the other procedures in this group, nor similar in terms of hospital resources. Similarly, 0084T does not belong in APC 162. The clinical and resource features of CPT 52282 and 0084T are more appropriately classified to APC 429. Alternately, these CPT codes (CPT 52282 and 0084T) should be reassigned back to APC 385 and grouped with other procedures that involve prosthetic urology devices.

CPT 52282 cystoscopy with insertion of urethral stent was moved from APC 385 for 2005 because CMS thought that a "urethral" stent was not a "prosthetic device." We strongly disagree.

> Prosthetic devices are defined for purposes of Medicare to include cardiac pacemakers, prosthetic lenses, breast prostheses (including a surgical brassiere) for post mastectomy patients, maxillofacial devices, and devices which replace all or part of the function of the ear or nose.
>
> A urinary collection system with a tube is a prosthetic device replacing bladder function in cases of permanent urinary incontinence. The Foley

catheter is also considered a prosthetic device when ordered for a patient with permanent urinary incontinence (see CMS hospital manual 228.4).

Collagen implants injected into the urethra for treatment of urinary incontinence are also considered a prosthetic device (see CIM 65-9) because the implant facilitates the proper functioning of the urethral sphincters.

By way of background, the urethral stent is a device that keeps the urethra open and thereby ensures proper function and drainage of urine from the bladder. For this reason, we believe that the urethral stent fits the Medicare definition of a prosthetic device and should be reassigned to APC 385 or alternately assigned to APC 429. APCs 385 or 429 are the most appropriate APC based on the hospital resources (costs) involved and the clinical features. Furthermore, CMS's own definition of prosthetic devices and examples supports moving CPT 52282 to APC 385 or alternately APC 429.

Under OPPS, procedures are intended to be grouped to APCs according to clinical complexity, resource intensity, design and cost. In keeping with this policy, we strongly urge CMS to reassign CPT code 52282 to APC 385 or APC 429. Such a change will produce more accurate reimbursement for hospitals and thus ensure that hospitals are paid consistently with other procedures under HOPPS. Finally, reassignment of CPT 52282 is necessary to achieve clinical cohesiveness in each of the respective APCs, appropriate payment, and ensure continued beneficiary access to these needed therapies.

II. Proposed AMA CPT Code requirements for New Technology APC applications

AMS joins AdvaMed and others in objecting to CMS's proposal to require that an application for a code for new technology be submitted to the American Medical Association CPT Editorial Panel before CMS will accept a New Technology APC application for review.

AMS has a number of concerns with this proposed policy. First, imposition of this added requirement will impede, rather than enhance, the recognition of new technologies by imposing delays on CMS decisions. Second, the CPT code development process is not public. The AMA CPT Editorial Panel is a private organization. Neither the deliberations by AMA on granting new CPT codes, nor the bases for their decisions, are open to the public. There is no medical industry representation on the AMA CPT Editorial Panel. The AMA CPT Editorial Panel is not subject to the protections of the Administrative Procedures Act, the Freedom of Information Act or the Federal Advisory Committee Act, and thus may not be accountable as are other agencies that are responsible for public policy decisions.

Category I codes are usually assigned to a procedure that has become an accepted standard of care. This defeats the purpose of adoption of new technology. A New Technology APC would likely be assigned a Category III "emerging technology" code due to lack of availability of sufficient data. This means that the new service may not receive reimbursement by local Medicare carriers, commercial payors and fiscal intermediaries, until a Category I code has been assigned.

Accordingly, AMS recommends that CMS eliminate this proposed requirement to submit a CPT application to the AMA prior to submitting a New Technology APC application.

III. Inpatient Procedures -Status Indicator Changes Needed for Prolapse Procedures

Currently, CPT codes 57282 and 57283 which describe procedures to repair vaginal prolapse are assigned "C" status indicators. The "C" status indicator means that CMS has determined that the procedures are "inpatient services that are not payable under the OPPS."

CMS reviews the inpatient only list on an annual basis. For 2006, CMS has proposed removing 25 procedures from this list so that these procedures are payable under OPPS. In addition to the procedures already listed, we request that CMS add 57282 Repair of vaginal prolapse and 57283 Colpopexy, intraperitoneal and change the status indicators so that these procedures are also payable under OPPS. Based on information provided by our hospital customers and clinical experts both 57282 vaginal prolapse and 57283 colpopexy meet the criteria for assignment to an APC. Specifically –

- These procedures related to codes that CMS has already removed from the inpatient list (e.g., CPT codes 57284 Repair paravaginal defect including cystocele ...and vaginal prolaspse;
- Most outpatient departments are equipped to provide the services to the Medicare population;
- These procedures can be appropriately and safely performed in an outpatient setting; and
- These procedures are currently being performed in hospitals on an outpatient basis.

We also recommend that CMS assign CPT codes 57282 and 57283 to APC 202. APC 202 already includes CPT code 57284 paravaginal defect repair including repair of cystocele, stress urinary incontinence and/or incomplete vaginal prolapse. Therefore, assignment to APC 202 would maintain the clinical homogeneity of this APC.

IV. Payment for Prosthetic Urology and Device-Related APCs

AMS joins CAPU in urging CMS to continue to examine cost data to set 2006 payment rates for APCs 385 and 386. As CMS discussed in the preamble to the Proposed Rule, hospitals do not appear to routinely include the charges for "devices" when they bill for device-dependent services in the device-dependent APCs including APCs 385 and 386. Furthermore, hospital billing and charging for prosthetic urology devices which involve multiple components has been particularly challenging for hospitals, in part, due to the methodology used to calculate "hospitals costs."

For this reason, AMS has provided actual invoices to CMS demonstrating that hospital costs for many prosthetic urology devices range from about **$6,500 to $7,895**, inclusive of all rebates, contracts, group purchasing agreements, for the past two years. We wish to reiterate that AMS manufactures well over 80% of devices used with the procedures assigned to APCs 385 and 386. Thus, while the external data furnished by AMS is significantly representative of hospitals' actual acquisition costs for prosthetic urology devices, CMS has not used external data to benchmark payment for prosthetic urology procedures in APCs 385 and 386.

AMS feels strongly that CMS should apply the same standard for all device-dependent APCs. Furthermore, if CMS sets the floor on 2006 payment rates at 100% of the 2005 payment rates plus the basket update, we believe CMS must use external data to appropriately adjust the payment rates for APCs 385 and 386 (prosthetic urology). Going forward, we recommend that CMS apply any policy on payment for device-related APCs in a he uniform fashion. Uniform application is needed to correct and stabilize APC payment for device-dependent procedures such as prosthetic urology and ensure that beneficiaries have uninterrupted access to these needed therapies.

* * *

As always, we are grateful for the opportunity to provide comment to CMS on the proposed OPPS rule. If you have any questions about these comments, or if you would like additional information, feel free to contact Gary Goetzke at 952-930-6155 or our reimbursement counsel, Gail Daubert, Esq. at 202.414.9241.

Sincerely,

Gary Goetzke

Gary Goetzke
Senior Director
Health Care Affairs

cc: Jim Hart, CMS
John Mulcahy, Chairman, CAPU

180

The Coalition for the Advancement of Prosthetic Urology
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September 16, 2005

APC/Gen
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Brn by Hand

Via Hand Delivery
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Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
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Washington, DC 20201

Re: **CMS -1501-P** Proposed Changes to the Hospital Outpatient PPS for CY 2006: Device-Related APCs, Prosthetic Urology – APCs 163, 385 and 386

Dear Dr. McClellan:

The Coalition for the Advancement of Prosthetic Urology ("CAPU") wishes to express its appreciation for the opportunity to comment on the July 25, 2005 Proposed Rule on Changes to the Medicare Hospital Outpatient Prospective Payment System ("OPPS") and Calendar Year 2006 Payment Rates (70 Fed. Reg. 42,674). CAPU is a national organization that includes leading clinical experts and researchers in prosthetic urology. CAPU appreciates the efforts CMS has made in the development of the proposed OPPS rule and we are keenly interested in the changes recommended in the Proposed Rule concerning payment rates for prosthetic urology devices and procedures.

Our comments this year primarily relate to CMS's process for establishing APC rates for device-related APCs and the clinical and resources homogeneity of the prosthetic urology family of APCs. Our recommendations are intended to ensure that OPPS payment for these devices and services supports high quality care for Medicare patients.

Our recommendations are summarized briefly below:

- Clinical and Resource Homogeneity.

1. **Reassign CPT code 52282 *Cysto with insertion of urethral stent* to APC 429 Level V Cystourethroscopy or APC 385 Prosthetic Urology**. CPT code 52282 cystoscopy with insertion of urethral stent is currently assigned in APC 0163 but it is neither clinically similar to the other procedures in this group, nor similar in terms of hospital resources. The clinical and resource features of CPT 52282 are more appropriately classified to APC 429. Alternately, CPT code 52282 should be reassigned back to APC 385 (where it was assigned in 2004) to maintain the clinical homogeneity and resource similarity required by the APC system.

2. **Reassign CPT code 0084T *Insertion of temporary prostatic urethral stent* to APC 429** with CPT 52282 or assign this procedure to APC 385 Prosthetic Urology. 0084T is currently assigned to an inappropriate APC and should be grouped with other procedures also involving stents and prosthetic devices.

- Device-Related APCs – Payment.

  1. We support proposals to appropriately capture device and technology costs. However, at this point, we object to proposals that request CMS to set "payment" floor at 100% of the current rates for a selective group of device-related APCs that have received preferential treatment under HOPPS for the past several years, namely the APCs for Neurostimulators, and Cardiac Defibrillators.

  2. CAPU and others have repeatedly noted that the payment rates for prosthetic urology (APCs 385 and 386) fall short of covering hospital costs.

  3. Furthermore, despite the APC Advisory Panel's recommendations to use external data to appropriately adjust the payment rates for prosthetic urology, CMS has declined to do so. At the same time, CMS has used external data to increase payment for neurostimulators and cardiac defibrillators. For this reason, we are opposed to proposals that include special payment concessions for a select group of APCs that has routinely received preferential treatment under the HOPPS, especially when these increases will likely lower the payment rates for prosthetic urology.

- Payment for device-dependent APCs 385 and 386.

  1. Appropriate payment for prosthetic urology procedures is critical to ensure that Medicare beneficiaries have access to these important therapies.

  2. HOPPS payment for prosthetic urology has been inadequate under the OPPS for the past several years and while the proposed payment rates project an increase for 2006, the rates, if finalized, would still fall short of adequate reimbursement for hospitals.

  3. **CAPU urges CMS to continue to carefully examine the charge and cost data used to set payment for the prosthetic urology APCs.**

APC Reassignment for Urethral Stent Procedures (CPT 52282 and 0084T)

Under OPPS, procedures are intended to be grouped to APCs according to clinical complexity, resource intensity, design and cost. CPT code 52282 is currently assigned to APC 0163 but it is neither clinically similar to the other procedures in this group, nor similar in terms of hospital resources. Similarly, 0084T does not belong in APC 162. The clinical and resource features of CPT 52282 and 0084T are more appropriately classified to APC 429. Alternately, these CPT codes (CPT 52282 and 0084T) should be reassigned back to APC 385 and grouped with other procedures that involve prosthetic urology devices.

CPT 52282 cystoscopy with insertion of urethral stent was moved from APC 385 for 2005 because CMS thought that a "urethral" stent was not a "prosthetic device." We strongly disagree.

> Prosthetic devices are defined for purposes of Medicare as devices which replace all or part of the function of a body part or organ.

> A urinary collection system with a tube is a prosthetic device replacing bladder function in cases of permanent urinary incontinence. The Foley catheter is also considered a prosthetic device when ordered for a patient with permanent urinary incontinence (see CMS hospital manual 228.4). Collagen implants injected into the urethra for treatment of urinary incontinence are also considered a prosthetic device (see CIM 65-9).

The urethral stent is a device that keeps the urethra open and thereby ensures proper function and drainage of urine from the bladder and, consistent with Medicare policy should also be considered a prosthetic device.

For this reason, we believe that the urethral stent fits the Medicare definition of a prosthetic device and should be reassigned to APC 385 or alternately assigned to APC 429. APCs 385 or 429 are the most appropriate APC based on the hospital resources (costs) involved and the clinical features. Furthermore, CMS's own definition of prosthetic devices and examples supports moving CPT 52282 to APC 385 or alternately APC 429.

* * *

As always, we are grateful for the opportunity to provide comment to CMS on the proposed OPPS rule. If you have any questions about these comments, or if you would like additional information, feel free to contact our reimbursement counsel, Gail Daubert, Esq. at 202.414.9241.

Sincerely,

John Mulcahy

John Mulcahy, M.D., Chairman
CAPU

cc: Jim Hart, CMS
CAPU Board (via email)
Gail Daubert, Esq.

181

Pymt Rate
APC for
APC D-5

Heyssler
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Hart
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MEDICAL TECHNOLOGIES, INC.

September 15, 2005

Via Messenger / Hand Delivery

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Rm. 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1501-P Proposed changes to Hospital Outpatient PPS for 2006:
Urgent Need to Assign Endovenous Ablation Therapy to Appropriate APC - $2,800

Dear Administrator McClellan:

On behalf of VNUS Medical Technologies, Inc. (VNUS), we are pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed changes to the Hospital Outpatient Prospective Payment System (HOPPS) for 2006 (70 Fed. Reg. 42,674). VNUS is the leading manufacturer of the technology used in endovenous ablation therapy of incompetent veins (e.g., varicose ulcers and venous insufficiency). For Medicare patients this is a crucial therapy to reduce painful swelling in the legs, restore mobility and function, and enable patients to regain and enjoy a high quality of life.

The AMA CPT Panel established new CPT codes for endovenous ablation therapy using radiofrequency (RF) technology in 2004. In the Final 2005 HOPPS rule, CMS announced the "interim" APC assignment for these procedures, subject to comment. VNUS submitted timely comments on the interim APC assignment, specifically requesting that CMS establish two new APCs for endovenous ablation procedures. We recommended Level I Endovenous Ablation Procedures be assigned to laser ablation (CPT Codes 36478 and 36479) and Level II Endovenous Ablation Procedures be assigned to radiofrequency ablation (CPT Codes 36475 and 36476), effective with the next HOPPS update. CMS did not respond to these comments. Accordingly, we reiterate the request that CMS establish a new APC (or reassign these procedures) so that the HOPPS payment is consistent with the resources involved with endovenous RF ablation, and at a level that supports high quality care for Medicare patients.

We request an APC with a payment rate of approximately $2,800 for RF ablation (CPT 36475 and 36476) and $2,300 for laser ablation. In the following sections we summarize the evidence that supports the request for APC reassignment and payment increase for RF ablation.

Currently, endovenous RF ablation therapy procedures are assigned to the same APC as traditional vein stripping procedures. While procedure times are similar between vein stripping and RF ablation procedures, time is the only similarity. This APC grouping is clinically inappropriate for the following reasons:

- Endovenous RF requires ultrasound imaging guidance – vein stripping does not;
- RF requires a special disposable RF catheter – vein stripping does not;
- RF requires special capital equipment – vein stripping does not;
- RF requires a vascular or ultrasound technician – vein stripping does not; and
- Endovenous RF requires additional operating room time for vein mapping, catheter placement, infiltration of special tumescent solution – vein stripping does not.

By establishing distinct procedure codes in 2004, the AMA CPT Panel acknowledged that endovenous RF ablation procedures are very distinct from both vein stripping and endovenous laser ablation procedures. Also, strong, solid clinical evidence (level one) clearly demonstrates that patients suffering from venous insufficiency treated with RF ablation experience significant clinical benefits compared to conventional vein stripping procedures. Data from three published randomized trials comparing RF ablation to vein stripping support this conclusion. Five year clinical data recently published continues to demonstrate that RF ablation offers patients long-term safety, durability and efficacy.[1]

The differences between endovenous RF ablation therapy and vein stripping are also documented by CMS with respect to the non-facility practice expense relative value units (PE RVUs) assigned to these procedures:

CPT code	Non-facility PE RVUs
36475 endovenous RF ablation therapy	48.94
37720 removal of leg vein	N/A
37730 removal of leg vein	N/A
37735 removal of leg veins	N/A

Non-facility PE RVUs are generally reflective of the hospital outpatient "technical" component of procedures. The fact that CPT codes 37720-37735 do not include non-facility PE RVUs is further support that these procedures should not be assigned to the same APC under HOPPS.

In fact, RF ablation procedures are more clinically similar to procedures in APC 86 Ablate heart dysrhythm focus ($2,614), especially with respect to resources, and, therefore, CPT codes 33250 or 33251 could be used as reference procedures rather than vein stripping.

Our comments and recommendations are as follows:

- The CPT codes for endovenous ablation therapy are as follows:

  36475 *endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency, first vein treated*

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1 Merchant RF, Pichot O, for the Closure study group. Long-term outcomes of endovenous radiofrequency obliteration of saphenous reflux as a treatment for superficial venous insufficiency. J Vasc Surg 2005, 42(3): 502-509.

36476 endovenous ablation therapy ..., inclusive of all imaging guidance ..., second and subsequent veins treated in a single extremity through separate access sites.

- CMS inappropriately assigned endovenous RF ablation procedures to APC 92 with "vein stripping" procedures with a proposed payment of $1,564.

- Endovenous RF ablation procedures should be assigned to an APC that pays approximately $2,800 based on the direct costs of the equipment and disposable RF device and accessories needed to perform a procedure. Specific examples of costs associated with the RF ablation procedure include:

  - RF ablation catheter $ 680.00
  - Procedure kit of accessories & vein access sheath $ 98.50
  - RF Generator $25,000.00
  - Portable duplex ultrasound system $40,000.00

Data from the 2006 NPRM summary file of practice expense cost inputs cites the following costs associated with endovenous ablation procedures:

HCPCS	Description	Supply Cost NF	Equip Cost NF
36475	RF Ablation, 1st vein treated	$998.82	$144.04
36478	Laser Ablation, 1st vein treated	$881.70	$159.02

Since the RUC committee's last review, the supply cost for both endovenous ablation procedures have decreased for specifically the disposable RF catheter and the laser fiber kit. The RF catheter which is listed for $725 has decreased $45 in average sales price to $680 and the laser fiber kit which is listed for $677 is routinely sold for $325. Therefore, the current supply cost NF for RF ablation procedures is reduced by $45 from $998.82 to $953.83 and the current supply cost NF for laser ablation procedures is reduced by $325 from $881.70 to $556.70 (see 70 Fed. Reg. 45,764 (Aug. 8, 2005).

Procedure times between vein stripping and RF ablation are somewhat similar. However procedure times are different between RF ablation and laser ablation. The NPRM data file shows a 64 minutes intra-therapy time for RFA and 59 minutes for laser ablation. Therefore, the baseline procedure cost (prior to adjustments for supplies, equipment and ultrasound) for laser ablation can be computed as 59/64 = 92% of the cost of RFA procedure. When APC 92, vein stripping, is used as the baseline procedure cost ($1564) for RFA, then the procedure cost for laser ablation is 0.92 x $1564 = $1439.

- The CPT codes for endovenous RF ablation procedures specifically include the use of all imaging guidance which means hospitals cannot bill separately for the guidance as they do for most other procedures. This means that the APC payment should include the costs of hospital resources for imaging guidance which for RF ablation procedures typically involves the use of duplex ultrasound. The RUC committee data from the NPRM labor cost input file shows that a vascular technologist will on average have 52 minutes of intra-therapy time for an RF ablation procedure. In addition, the vascular technologist has both pre- and post-therapy time of about 15 minutes for moving and setting up the ultrasound system between the vascular lab and procedure room. This time is not reflected in the

NPRM labor file. Therefore, the total vascular tech time is approximately an average of 67 minutes. CMS has recognized the cost of conducting a duplex ultrasound diagnostic evaluation of the legs with CPT 93970 (APC 267) and provides an APC payment of $156 for that service which according to the NPRM labor cost input file is for 75 minutes of total therapy time. Prorating this payment to a 67 minute procedure time results in a cost of 67/72 x 156 = $145. We respectfully request that this cost is reflected in the assignment of CPT 36475 and 36476 to an APC code.

To determine the total resource-based cost of performing an endovenous ablation procedure, the vein stripping APC 92 cost of $1564 for the procedure time provides a baseline to which the following cost adjustments should be made.

- Reduce baseline procedure cost for faster laser ablation procedure
- Add the cost of the disposable supplies (after correcting for current prices)
- Add the cost of the equipment
- Add the cost of performing ultrasound imaging

Code	Description	Procedure Cost	Adjusted Supply Cost NF*	Equipment Cost NF	Ultrasound Imaging Cost	Total Cost
36475	RF Ablation, 1st vein treated	$1564	$953.83	$144.04	$145	$2807
36478	Laser Ablation, 1st vein treated	$1439	$556.70	$159.02	$145	$2300

*Supply Cost NF is from the 2006 NPRM file adjusted to a lower level to reflect current lower disposable prices

Therefore, we recommend that CMS assign endovenous RF ablation procedures to a new APC with a more appropriate payment (or reassign the RF ablation procedures to APC 86). Preferably, we urge CMS to use the above cost analysis incorporating adjusted 2006 NPRM Practice Expense Input data plus an additional $145 to reflect the cost of imagining guidance to establish two new clinical APCs with payment at minimum as follows:

APC xxx Endovenous Ablation Procedures, Radiofrequency - payment $2,800

36475 Endovenous RF, first vein – Level II Endovenous Procedures
36476 Endovenous RF, vein add-on – Level II Endovenous Procedures

APC xxx Endovenous Ablation Procedures, Laser - payment $2,300

36478 Endovenous Laser, first vein – Level II Endovenous Procedures
36479 Endovenous Laser, vein add-on – Level II Endovenous Procedures

We appreciate the opportunity to submit these comments and to work with CMS to implement these changes and ensure Medicare patients have access to endovenous ablation procedures in the hospital outpatient setting.

Should you have any questions, please contact me or our reimbursement counsel, Gail Daubert, at 202.414.9241, if we can provide further information to help expedite the proper APC assignment for these procedures.

Thank you for your consideration.

Sincerely,

Jennifer Ditlow
Director of Reimbursement
VNUS Medical Technologies, Inc.

Enclosure:

Comment letter on "Interim" APC assignment for endovenous ablation procedure

cc: James Hart, Director, Division of Outpatient Care, CMS

VNUS®
MEDICAL TECHNOLOGIES, INC.

January 13, 2005

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Rm. 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1427-FC Hospital Outpatient Final Rule with Comment: Urgent Need to Reassign Endovenous RF Ablation to Appropriate APC

Dear Administrator McClellan:

On behalf of VNUS Medical Technologies, Inc. (VNUS) and hospital outpatient departments using our technology, we are pleased to submit comments on the Centers for Medicare and Medicaid Services (CMS) final rule with comment: Medicare Program, changes to the Hospital Outpatient Prospective Payment System (HOPPS) for 2005 (69 Fed. Reg. 65682). Specifically, we commend CMS for promptly recognizing the new CPT codes 36475 and 36476 Endovenous Radiofrequency (RF) Ablation but strongly urge CMS to move these procedures to a new clinical APC, effective with the next HOPPS quarterly update in April.

A new clinical APC is needed to pay for these procedures appropriately, consistent with the resources needed to perform endovenous RF ablation, and at a level that supports high quality care for Medicare patients. Our recommendations are as follows:

- Establish two new APCs for endovenous ablation procedures with payment, at minimum, as follows:

  Level I Endovenous Ablation Procedures – payment $1,583[1]

  Level II Endovenous Ablation Procedures - payment $2,500

- Assign endovenous RF ablation procedures (CPT codes 36475 and 36476) to Level II Endovenous Ablation Procedures (payment $2,500)[2]

Endovenous RF ablation is a procedure that treats various venous conditions of the extremities such as varicose ulcers and venous (peripheral) insufficiency. For elderly Medicare patients this is a crucial therapy to reduce painful swelling in the legs, restore mobility and function, and enable patients to recover a high quality of life. VNUS is the leading manufacturer of the innovative radiofrequency ablation devices used to treat these conditions in the hospital outpatient setting. VNUS is pleased that CMS has included the new CPT codes for endovenous RF procedures in the HOPPS final rule. The CPT codes are as follows:

36475 Endovenous radiofrequency ablation, first vein

36476 Endovenous radiofrequency ablation, vein add-on

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[1] We recommend CMS assign CPT codes 36478 and 36479 laser procedures to Level I Endovenous Ablation Procedures.

[2] These distinct APCs and payment rates are supported by the clinical and resources differences between the procedures as evidenced in part by the higher non-facility practice expense RVUs assigned to CPT 36475 endovenous RF procedures under the Medicare physician fee schedule.

On an interim basis, subject to comment within 60 days of publication of the rule, CMS has assigned these two CPT codes to APC 92 with a payment rate of $1,538. This APC assignment is inappropriate for several reasons.

First, the APC payment amount fails to reflect the hospital resources for endovenous RF procedures. The procedure takes approximately **1.5 hours of operating room time** and involves RN and/or LPN staff plus the services of a vascular technician. The procedure necessitates that hospitals purchase a special RF generator **($25,250)** and duplex ultrasound **($40,000)**. In addition to these capital costs, hospitals' cost for the RF ablation catheter alone is **$725.00** with additional supplies costing another **$400** or more dollars.

Second, we understand that the Division of Outpatient Care used the vein stripping procedures as a reference for the APC assignment of endovenous RF procedures and we believe that this comparison is severely flawed for the following reasons:

- Endovenous RF requires ultrasound imaging and guidance – vein stripping does not;
- RF requires a special disposable RF catheter – vein stripping does not;
- RF requires special capital equipment – vein stripping does not;
- RF requires a vascular or ultrasound technician – vein stripping does not; and
- Endovenous RF requires additional operating room time for vein mapping, catheter placement, infiltration of special tumescent solution – vein stripping does not.

Surgeons across the country, as well as the American Medical Association CPT Panel, have acknowledged that endovenous RF ablation procedures are very distinct from both vein stripping and endovenous laser procedures. Endovenous RF ablation is also proven in published randomized clinical trials to provide patient benefits compared to traditional vein surgery.[3,4,5] Surgeons and hospital outpatient departments have also provided testimony that endovenous RF ablation procedures involve substantially more operating room time and hospital resources than both vein stripping and endovenous laser procedures. In fact, endovenous RF ablation procedures are more clinically similar to procedures in APC 83 percutaneous valvuloplasty ($3,154) and procedures in APC 86 Ablate heart dysrhythm focus ($2,567), especially with respect to time and resources, and that intracardiac ablation procedures (CPT codes 33250 or 33251) should be used as the reference procedure rather than vein stripping procedures.

Third, CMS's assignment of endovenous RF Ablation procedures to APC 92 Level I Vein Ligation which includes predominately vein stripping procedures is inconsistent with the charge/cost data submitted by hospitals and analyzed by CMS for pass-through code C1888 catheter, ablation, which expired Dec. 31, 2004. The C1888 code ablation catheter describes the device used in endovenous RF ablation procedures. The C-codes were established to describe new technology devices so that CMS could gather accurate charge and cost data and when such data were available the additional costs associated with the new device were to be folded or bundled into payment for the procedure. However, the appropriate costs for C1888 ablation catheter were not bundled into APC 92 Vein Ligation

[3] Lurie at al, Eur J Vasc Endovasc Surg 2005;29:67-73.
[4] Lurie et al, J Vasc Surg 2003;38:207-14.
[5] Rautio et al, J Vasc Surg 2002;35:958-65.

when the endovenous RF ablation procedures were assigned to this APC. To demonstrate, we note the following

	2004 Payment	2005 Payment
APC 92 Level I Vein Ligation	$ 1,369.26	$1,538.27

This minimal increase in payment does not begin to appropriately reimburse hospitals for the costs associated with endovenous RF ablation procedures. As we pointed above, the RF ablation probe alone is **$725.00** with additional supplies unique to this procedure costing an additional **$400** or more dollars. Moreover, adding additional costs to APC 92 and bundling into the payment would overpay for the vein stripping procedures. Therefore, we are recommending that CMS assign these procedures to a new APC with more appropriate payment.

Finally, when VNUS met with CMS to explain in greater detail the clinical and resource (cost) features of endovenous RF ablation procedures and during that meeting recommended that CMS move these procedures into a new technology APC which appropriately reflected the costs for these procedures (see attached new technology application). In addition, VNUS, as well as hospital outpatient departments, have submitted both "cost information" and charge data for endovenous RF procedures which, at minimum, support assignment of these procedures to an APC with a payment rate of about $2,500 (see attached hospital charge data).

In short, placement in APC 92 is not only problematic economically for hospitals, but also an actual violation of CMS' two times rule, since based on the hospital charge data we examined, the resources (charges/costs) associated with endovenous RF ablation are more than two times the resources for other procedures in APC 92.

Therefore, we recommend CMS reevaluate the interim APC assignment for RF ablation procedures and use the hospital outpatient charge data submitted by VNUS and hospitals across the country to reassign these procedures to new clinical APCs with payment at minimum as follows:

APC xxx Level I Endoveneous Ablation Procedures[6] – payment $1,583

APC xxx Level II Endovenous Ablation Procedures - payment $2,500

36475 Endovenous RF, first vein – Level II Endovenous Procedures
36476 Endovenous RF, vein add-on – Level II Endovenous Procedures

Establishing new APCs with multiple levels for different therapeutic modalities based on the type of energy source and/or resources involved is consistent with CMS's long-standing practice and policy under HOPPS (e.g., benign prostatic hypertrophy therapies, thrombectomy procedures, and even vascular ligation procedures). Thus, we would strongly encourage CMS to act quickly and reassign endovenous RF ablation procedures effective with next quarterly update based on the hospital cost and charge data provided.

[6] We believe it would be appropriate to assign CPT codes 36478 and 36479 endovenous laser procedures to this APC. Endovenous laser procedures involve more resources and time than vein stripping but less than endovenous RF ablation procedures (see attached New Tech APC application describing these differences).

We appreciate the opportunity to submit these comments and to work with CMS to implement these changes and ensure Medicare patients have access to endovenous RF ablation procedures in the hospital outpatient setting. We will plan on contacting Cindy Read, Director, Division of Outpatient Care to review these issues in greater detail. Should you have any questions in the meantime, please contact me or our reimbursement counsel Gail Daubert at 202.414.9241 if we can provide further information to help expedite the proper APC assignment for these procedures.

We will contact Cindy Read, Director, Division of Outpatient Care, to arrange a meeting to review these issues in greater detail. Should you have any questions in the meantime, please contact me or Gail Daubert at 202.414.9241. Thank you for your consideration.

Sincerely,

William Perry

William Perry, Vice President, Marketing
VNUS Medical Technologies, Inc.

Enclosure:

1. New Technology APC Application for endovenous RF ablation procedures
2. Hospital charges: Arrowhead Community Hospital,

cc: Cynthia Read, CMS
Edith Hambrick, M.D., J.D., CMS
Carol Bazell, M.D. CMS
The Honorable Anna Eschoo

182

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September 12, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments on Radiopharmaceuticals under Medicare Proposed Rule for Hospital Outpatient Prospective Payment System

CMS – 1501- P; NonPass-Throughs

Dear Dr. McClellan:

Cardinal Health welcomes this opportunity to share its comments and recommendations to the Centers for Medicare and Medicaid Services (CMS) on the radiopharmaceutical payment provisions in CMS proposed rule on the Hospital Outpatient Prospective Payment System (HOPPS), 70 Fed. Reg. 42,674 (July 25, 2005).

Cardinal Health develops, manufactures, packages, and markets products for patient care; develops drug-delivery technologies; distributes pharmaceuticals, medical-surgical and laboratory supplies; and offers consulting and other services that improve quality and efficiency in healthcare. Our Nuclear Pharmacy Services (NPS) business compounds and dispenses radiopharmaceuticals for diagnostic and therapeutic use by nuclear medicine departments in hospitals and outpatient clinics. Specifically, Cardinal Health's NPS business operates 165 nuclear pharmacies throughout the U.S. that compound and distribute a wide variety of unit dose and bulk radiopharmaceuticals, operates fourteen cyclotrons that produce FDG and other radioisotopes and markets FDG produced by third parties in another thirteen areas. The radiopharmaceuticals we provide to hospitals diagnose and treat patients with a wide array of clinical conditions including oncology, cardiology, pulmonary, neurology, and musculoskeletal disease.

In brief, Cardinal Health recommends:

1. CMS use the cost to charge ratio for payment of radiopharmaceuticals to hospitals in 2006, utilizing the hospitals' general cost to charge ratio and not a department specific cost to charge ratio.

2. CMS institute a mechanism to recognize all the hospital's additional and significant costs needed for safe handling, disposal, and overhead.

3. CMS consider the continued use of a CCR methodology in 2007 or adopt another method which accurately calculates the hospitals' average acquisition cost or average price for the radiopharmaceutical, and fully accounts for the special costs of radiopharmaceutical overhead and handling.

4. CMS should not use average sales price (ASP), as it is currently defined and calculated, as a basis for determining payment for radiopharmaceuticals under HOPPS.

Our detailed analysis is presented below.

A. Use of Hospital general cost to charge ratios

Cardinal Health recommends that, during 2006, CMS use the hospitals' general cost to charge ratios, with some adjustments, as a reasonable proxy of the hospitals' average acquisition costs. CMS notes that the GAO reported purchase prices for nine radiopharmaceuticals were substantially lower than CY 2005 payment rates. 70 Fed. Reg. at 42,727. Further, CMS' intent is to maintain consistency, whenever possible, between 2005 and 2006 for radiopharmaceutical payment, because rapid reductions could adversely affect beneficiary access to services utilizing radiopharmaceuticals. Id. CMS observes that if Medicare pays for radiopharmaceuticals using charges converted to costs, CMS believes that payment based on costs would be the best available proxy for the average acquisition cost along with handling costs, until ASP becomes available, and more information on overhead costs is obtained. Based on these concerns, CMS is proposing to use hospital charges adjusted to costs in 2006.

Cardinal Health supports CMS use of hospital cost to charge ratio if the fiscal intermediaries utilize the hospitals' general cost to charge ratio and some mechanism is created to capture the overhead and handling costs.

Some hospital costs associated with radiopharmaceutical purchase and use are captured in hospital charges. However, the preparation, distribution, administration, and safe disposal of radiopharmaceuticals, along with necessary patient and hospital staff protection costs, are not uniformly or accurately reflected in hospital charges. These are quite complex and can vary from product to product. For these reasons, Cardinal Health makes two recommendations for 2006:

1. Use hospital general cost to charge ratios, not department specific CCRs; and

2. Include separate payment or a further adjustment for the additional costs associated with radiopharmaceutical handling and overhead costs.

It appears that hospital department specific CCRs are lower and more variable than hospital general CCRs. Department specific CCRs like radiology, pharmacy, or even medical supplies do not capture the complexity or pricing of radiopharmaceuticals, as well as a hospital general CCR. Thus, the hospital general CCR is a better proxy of hospital average acquisition costs.

B. Recognize overhead and handling costs

Overhead and handling of radiopharmaceuticals add costs that are not captured in charges for the radiopharmaceuticals, so that an additional factor or percentage needs to be included to ensure that payment is reasonable and meets the statutory standard of average acquisition cost.

C. Continued use of hospital General CCR in 2007

As discussed below, ASP is not currently a feasible alternative for payment for radiopharmaceuticals, so CMS should consider the continued use of the hospital general CCR, with some add on factors for overhead and handling costs in 2007.

D. Problems with ASP for radiopharmaceuticals

CMS is proposing to require radiopharmaceutical manufacturers to report ASP in 2006 and use ASP as a basis for payment under HOPPS for radiopharmaceuticals in 2007. Cardinal Health does not see ASP as feasible for radiopharmaceuticals and recommends that CMS explore other payment methods that are consistent with legal requirements and can be implemented more effectively from a practical perspective.

CMS acknowledges that § 303(h) of Pub. L. 108-173, the Medicare Modernization Act of 2003, exempts radiopharmaceuticals from ASP in the physician office setting. Congress exempted radiopharmaceuticals from ASP in the physician office setting because a unit dose ASP cannot be calculated for radiopharmaceuticals, as it can with standard, non-radioactive drugs. These same facts and legal barriers apply with equal force in the hospital outpatient setting. CMS provides an accurate description of the complexity of radiopharmaceutical preparation and pricing. 70 Fed. Reg. at 42728. Cardinal Health believes that the complexity and the uniqueness of the radiopharmaceutical distribution channel effectively eliminates ASP (as it is currently defined and calculated) as a basis for determining the average acquisition cost or average price of the drug.

ASP is calculated and reported by a manufacturer according to a "unit," which is the product represented by the 11-digit NDC code. For radiopharmaceutical products, the unit is a vial or a kit containing several vials of non-radioactive (i.e., "cold") product. Prior to dispensing, the pharmacy must radiolabel the vial (i.e., make it "hot") by adding a separate component, the radioisotope, which frequently comes from a separate manufacturer. The amount of isotope used can vary widely according to the type of drug being labeled, type of procedure, size and age of the patient and the amount of time between preparation of the dose and its scheduled administration. In addition, the number of doses that can be drawn from a single vial of product also varies widely according to the skill and efficiency of the pharmacist and the proximity of the pharmacy to the hospital, clinic or nuclear medicine department. As a result, the manufacturer's ASP of a unit of the radiopharmaceutical bears very little, if any, relationship to the cost of a unit dose administered to a patient. Furthermore, the manufacturer does not know, and has no way to estimate, the cost of that patient-specific dose

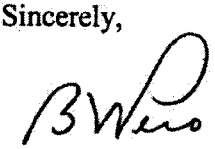
We further observe that the role of commercial radiopharmacies makes manufacturer's ASP even more irrelevant. Radiopharmacies, like our NPS business, purchase components for a unit-dose radiopharmaceutical product from many different manufacturers. We take a component, add one or more additional components, perform complicated preparation, dosing and quality-control procedures and dispense and deliver a patient-specific unit dose. Pricing for the end product can vary widely from hospital to hospital, depending upon volume, location, and whether the end product is delivered on a standard or emergency basis. We do not generally report any end-user customer pricing information to our suppliers and, in many instances, would not do so for antitrust law compliance purposes. We observe that manufacturers cannot generate an end product ASP.

One alternative would be for CMS to obtain ASP information from commercial radiopharmacies, like Cardinal Health, but that alternative does not seem to be possible under the current statutory and regulatory framework. Currently, the definition of "manufacturer" specifically excludes wholesale distributors and retail pharmacies licensed under state laws. 42 U.S.C. §13968-

8(K)(5); 42 C.F.R. § 414.802. To our knowledge, all commercial radiopharmacies are licensed as pharmacies under state law and many, including our own, are also licensed as wholesale distributors. Furthermore, manufacturers appear to be exempt from reporting radiopharmaceutical ASP (69 Fed. Reg. 17,935 (April 6, 2004)), and radiopharmacies are likewise exempt from ASP reporting by CMS regulation – 42 C.F.R. § 414.802. We do not believe there is a compelling reason to reverse CMS' policy and start a new process. Instead, CMS should continue the use of CCR in 2007 with adjustments and calculations to make this approach generate appropriate and fair payments for hospitals.

Cardinal Health is a member of the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR). We support the recommendations made in comments submitted by CORAR. Cardinal Health thanks CMS for this opportunity to share its concerns and suggestions on HOPPS payment for radiopharmaceuticals, and urges CMS to adopt the recommendations presented above.

Sincerely,



Brian V. Pero, Esq.
Assistant General Counsel
Nuclear Pharmacy Services
Cardinal Health, Inc.

cc: James Hart (CMS)
Kenneth McKusick, M.D. (Nuclear Medicine APC Task Force)
CORAR

183

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August 25, 2005

By U.S. Mail
Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

RE: **CMS-1501-P** Changes to the Hospital OPPS for CY 2006 -
Stereotactic Radiosurgery, Proton Beam Therapy, Kv X-ray Guidance, and New Technology APC Application Requirements

Dear Administrator McClellan,

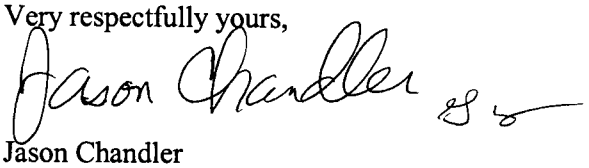
On behalf of BrainLAB AG and its U.S. based subsidiary, BrainLAB, Inc. (collectively, "BrainLAB"), I appreciate this opportunity to provide comments on the proposed rule for the Hospital Outpatient Prospective Payment System ("HOPPS") for Calendar Year 2006. BrainLAB is the technology leader in the manufacture of advanced medical systems for neurosurgery, orthopedic surgery, ear, nose and throat surgery, and radiation therapy. Since 1989, BrainLAB has pioneered the use of 3D renderings of CT and MR images to improve the accuracy of neurosurgical procedures and reduce their invasiveness. BrainLAB imaging, guidance, and neurosurgery products are used to treat Medicare patients at leading medical institutions across the United States and all over the world. Our primary products add significant clinical value to stereotactic radiosurgery ("SRS") stereotactic radiotherapy ("SRT") and Intensity-Modulated Radiation Therapy ("IMRT"). SRS, SRT, and IMRT are collaborative medical procedures between neurosurgeons and radiation oncologists that involve radiation energy from a linear accelerator ("LINAC") and/or Cobalt 60 to treat cancerous tumors and lesions, throughout the body. Where previously patients faced the prospect of an invasive surgery as the sole treatment for certain cancerous tumors and lesions, SRS, SRT, and IMRT now provides a non-invasive option and can be conducted on a hospital outpatient basis. Our comments and recommendations are as follows:

- **Stereotactic Radiosurgery**. BrainLAB supports CMS's proposal to delete *G0242 multi-source photon SRS, Cobalt-60 plan* ... and *G0338 LINAC- based SRS, plan* ... and instruct hospitals to report all of the available CPT codes that most accurately reflect the services provided (e.g., CPT codes 77295 77300, 77370, 77315, etc.).

- CMS has also requested comments on whether it is appropriate to combine cobalt planning (G0242) and cobalt delivery (G0243) together into a single procedure code based on the recommendation of one requestor. BrainLAB supports the position of the American Society for Therapeutic Radiology and Oncology ("ASTRO") that a new procedure code for cobalt planning and treatment is not necessary and that establishing such a code would only cause more confusion for hospital coders and

Please feel free to contact me at 440.213.3951 or Gail Daubert, our legal counsel, at 202.414.9241 if you or your staff members require additional information.

Very respectfully yours,



Jason Chandler
Director, Business Development

CH01/ 12438752.1

August 25, 2005

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

RE: CMS-1501-P Proposed Changes to Medicare Hospital Outpatient PPS for CY 2006 Request Assignment Computer-Assisted Orthopedic Surgery to APC 302 and Correction for APC 46 2-times Rule Violation – Orthopedic External Fixation

Dear Administrator McClellan:

On behalf of the Alliance for Orthopedic Solutions, we are pleased to submit comments on the proposed rule: Medicare program, changes to the Hospital Outpatient Payment System (HOPPS) and Calendar Year 2006 payment rates (70 Fed. Reg. 42,674). Alliance members include leading clinical experts dedicated to high quality clinical care, education, and research in Orthopedics, as well as the leading developers and manufacturers of orthopedic devices. The Alliance is pleased with several of CMS's proposed changes for HOPPS and supports CMS's efforts to use additional claims for purposes of setting relative weights and payment. However, we have several concerns with the hospital outpatient payment for orthopedic computer assisted navigational procedures and orthopedic procedures that involve external fixation devices. Our comments are discussed in detail below.

I. **Assign Orthopedic Computer Assisted Navigational Procedures to APC 302** with CPT 61795 Stereotactic Computer Assisted Volumetric (Navigational) Procedure

Orthopedic computer assisted navigational procedures or CAS involves using digital images as a map to improve the accuracy, mechanical alignment, kinetic alignment and outcomes of various orthopedic procedures. As you may know, computer assisted navigation creates a spatial correlation between radiologic data (from computed tomography [CT], magnetic resonance imaging [MRI] and/or fluoroscopy) and the real-time position of instruments and reference frames that are attached to a patient's bone during an orthopedic surgical procedure. The clinical value of computer assisted navigational procedures is widely recognized in the clinical community by many specialties and practitioners, including neurosurgery, spine, orthopedics, head and neck and ENT.

CMS has appropriately recognized and established payment for CPT 61795 computer assisted navigational procedures (spine, neuro, and extracranial) by assigning CPT 61795 to APC 302 with a proposed payment of $272. Unfortunately, the CPT codes for orthopedic computer assisted navigational procedures (0054T, 0055T, and 0056T) have been overlooked and have not been assigned to an APC even though "orthopedic" computer assisted navigational procedures use the same resources as the spine and neurological computer assisted navigational procedures (CPT 61795).

Accordingly, we urge CMS to:

(1) Assign <u>orthopedic</u> computer assisted navigational procedures to the same APC as computer assisted navigational procedures for spine, extracranial, and cranial procedures – that is APC 302 or

(2) Establish a new APC for computer assisted navigational procedures that includes CPT codes 61795, 0054T, 0055T, and 0056T with a payment rate of $272.

As explained in greater detail in the following sections, computer assisted navigational procedures for orthopedic surgery involves the same hospital outpatient resources as other computer assisted navigational procedures and for this reason, CMS should apply the same standards and payment policy to orthopedic CAS navigational procedures that have been established for spinal and extracranial CAS navigational procedures to ensure that Medicare patients receive the benefits of this technology for all types of procedures.

Description of CAS Navigational Orthopedic Procedures

Hospital Resources/Costs. Computer assisted navigational orthopedic procedures require standard surgical equipment **plus** specific high-technology devices and equipment including, among other things:

- computers,
- specialized planning software,
- infrared cameras,
- infrared markers and/or beacons,
- registration devices,
- special orthopedic instrumentation (e.g., retractors, reamers, implant holders, etc.)
- fluoroscopy, and
- computer monitor screens.

Overview. Computer assisted navigational procedures for orthopedics (like other computer assisted navigational procedures) is in effect a GPS system for surgeons. Just as drivers use GPS to find their way on the road, surgeons depend on computer assisted navigational technology to confirm the position of instruments in a patient's body, calculate trajectories, and choose the appropriate surgical strategy. The technology has enabled physicians to quantify findings less subjectively by providing measurement tools adequately tailored for different assessment activities and surgical procedures. Computer assisted navigation provides real time geometrical relationships of instruments and implants relative to a patient's anatomical structures. This, in turn, permits precise reconstruction in orthopedic procedures in combination with more minimally invasive surgical operations which can provide substantial clinical benefits to patients, i.e., faster rehabilitation, shorter hospitalizations, outpatient surgery rather than inpatient, etc.

Pre-Operative. CAS navigational procedures involve several steps. First, pre-operatively, anatomical information is collected before the operation generally in the form of a CT or MRI. The data is stored and transferred in the appropriate format and loaded onto the system at the hospital where the surgery will be performed. Using this information, surgeons can begin their pre-operative planning on a computer that has specialized surgery planning software and connection to the web or central computer data system which allows for transfer of the CT or MR images. The pre-operative computer planning helps the surgeon choose the surgical strategy after assessing the patient's anatomy from the CT/MR data. [Note hospitals must purchase specialized planning software for CAS.]

Intraoperative. Intraoperatively images are taken to visualize certain anatomical landmarks in the operating room at the time of surgery is performed. The intraoperative images generally involve the use of a specially modified fluoroscopy unit. The modified fluoroscopy unit is maneuvered during and throughout the procedure to obtain the images. As the images are acquired, the data is transferred directly to a computer through a hard-wired connection. CAS generally requires considerable pre-operative planning as well as the acquisition of the images.

Digital/Computer Registration of Anatomical Landmarks. Registration is the process of determining the geometric correspondence between the surgical plan and the patient's bones. Registration is done in the operating room and is generally accomplished by a two-step process. In the first step, the surgeon

attaches a "registration guide"[1] to the patient and identifies key anatomical landmarks (up to about 14 or more) for the computer according to a pre-determined sequence using "infrared light-emitting diode markers" positioned for the special "optical camera." The computer then displays a suggested position and orientation of the measurement probe with respect to the key anatomical landmarks. In the second step, the surgeon sets up the resection guides and checks to see if the "resection" is correct prior to actually resecting bone, thus ensuring proper positioning of resection guides the patient. If the "trial" cut is off, the surgeon can make some adjustments, and re-check the "cut." These trial "cuts" allow the surgeon to view the alignment as it is shown on the computer screen in real time. The accuracy of the registration process is fundamentally important to achieve accurate alignment and improve clinical outcomes.

Final Steps. The final steps vary slightly according to the procedure. For joint replacement, the final steps are to assess joint tension and balance using the computer prior to final implantation of the prosthesis. The graphical representation provided by CAS allows for substantial improvement (in real time) of final implant positioning and sizing. This requires the surgeon to interpret data provided by the computer and make decisions based on data input that are not required when CAS is not used.

It is important to recognize that computer assisted navigational technology (equipment) generally includes a full suite of software applications for (1) cranial, (2) spine, (3) ENT, and (4) orthopedic procedures. Thus, hospitals' costs for the equipment needed to furnish these different types of computer assisted navigational procedures are identical. For this reason, CPT codes 0054T, 0055T, and 0056T, computer assisted navigational procedures for orthopedics, should be assigned to the same APC that CPT code 61795 computer assisted navigational procedure (spine, neuro, and extracranial).

At present, CPT code 61795, computer assisted navigation for spine and neuro procedures, is assigned to APC 302 with a proposed payment rate of $272. Payment for computer assisted navigational procedures should be equitable and appropriate to ensure hospitals can financially afford to provide the full range of treatment options to Medicare patients on an outpatient basis. Patients should have access to the full spectrum of computer assisted navigational procedures and right now reimbursement discrepancies limit this access.

Accordingly, on behalf of hospitals across the country that are using computer assisted navigation for other orthopedic procedures, we request that CMS act promptly to **assign CPT codes 0054T, 0055T, and 0056T to APC 302**. This action is needed to ensure that beneficiaries have access to this technology for all types of procedures that require the precision associated with this technology.

II. Distinguish Procedures Using Fracture Fixation to Correct Violation of 2-Times Rule for APC 46

CMS must take certain measures to ensure that hospitals receive appropriate and adequate payment for orthopedic fracture fixation procedures under HOPPS. By way of background, the CPT codes that describe orthopedic fracture fixation procedures include the phrase "with or without internal or external fixation devices." As a result of these vague CPT code descriptors, CMS and hospitals have faced some unique coding and payment issues for orthopedic procedures involving external fixation devices. CMS has acknowledged that the current APCs violate the 2-times rule and has supported new CPT codes but the AMA CPT Panel and the Medical Specialty Groups do not want to create almost 100 new CPT codes, especially because the coding and payment issues impact only the institutional provider who purchases and pays for the fracture fixation devices.

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[1] Note physicians may use more than one registration device and the total number of such devices depends upon the specific need for the particular orthopedic procedure. For example, physicians may also drill and screw in a "femoral" and an "acetabular" registration device for hip procedures.

The key concern of the Alliance involves equitable payment to hospitals under HOPPS. Therefore, the Alliance urges CMS to take the steps necessary to implement a correction rather than delegate the issue to another private organization that does not have responsibility or authority over Medicare payment. The bottom line: the current configuration of APC 46 significantly underpays procedures that involve external fraction fixation devices. The cost for an external fixation device can range from $3000 for a unilateral fixation device to $6000 for a multiplane fixation device. Thus, the device costs are significantly higher than the payment for APC 46.

Our recommendations to more appropriately align the procedures both on the basis of clinical similarity and resource use are as follows:

- CMS should implement a policy to distinguish procedures that involve external fixation devices. For example, CMS could advise hospitals to bill one of two CPT codes:
  - CPT 20690 Application of a uniplane, unilateral, external fixation system or
  - CPT 20692 Application of a multiplane, unilateral, external fixation system

- A fracture procedure billed together with a CPT code for application of a fixation system would be assigned to an APC that CMS could establish specifically for "fracture procedures with fixation devices."

- CMS could establish one or two new APCs for fracture fixation procedures that are billed together with a CPT code for application of fixation device (i.e., CPT codes 20690 and 20692) and thereby eliminate the 2-times rule violation, preserve clinical homogeneity and more appropriately reimburse hospitals.

- If CMS establishes two APCs, one APC should include lower extremity fractures with application of an external fixation devices and the second APC should include upper extremity fracture procedures with application of external fixation devices.

  If CMS adopts this recommendation, the agency would also need to eliminate the correct coding initiative ("CCI") edit in the hospital outpatient software.

These recommended changes are reasonable mechanisms that will enable CMS to distinguish the more resource- intense fracture fixation procedures from the less costly casting procedures and thereby refine the APC configuration to eliminate the 2-times rule violation. The coding edits and changes would also be easy to implement – the codes already exist and the CCI edits are frequently updated. Finally, we believe that correct coding is more likely to occur if hospitals are required to report one or two codes for the fixation device.

The Alliance has presented alternative solutions to CMS to correct the two-time rule violation and ensure appropriate hospital reimbursement (see attached). We believe that Medicare beneficiaries may be denied access to appropriate treatment for fracture fixation if CMS continues to delay implementing a correction.

We appreciate the opportunity to submit these comments and we look forward to working with CMS directly in order to make payment to hospitals for orthopedic procedures equitable and appropriate.

Sincerely,

Gail Daubert

Gail L. Daubert, Esq.
Counsel for the Alliance

cc: Jim Hart, Director, Division of Outpatient Care
Edith Hambrick, M.D., J.D. CMS Medical Officer

Alliance for Orthopedic Solutions

August 17, 2004

Re: APC Advisory Panel Meeting
Restructuring APC for Orthopedic Fracture Fixation Procedures – APC 46

The Alliance for Orthopedic Solutions (Alliance) is pleased to submit comments to the APC Advisory Panel on Ambulatory Payment Classifications (APCs).

Alliance members include leading orthopedic surgical specialists, patient advocates and principal manufacturers and distributors of orthopedic fracture fixation devices. The Alliance is dedicated to high quality clinical care, education, and research in orthopedic care and ensuring that Medicare patients have access to the full range of orthopedic therapies and treatments.

Last year the Alliance presented information to the APC Advisory Panel on the need to restructure and create two new APCs for orthopedic procedures that involve external bone fixation devices. The Panel supported the Alliance's position and recommended that CMS review the matter. Although CMS received a summary of the claim file data which demonstrated that APC 46 violated the 2-times rule, CMS has maintained the current APC structure.

Our primary concern with the continued use of this APC structure is that these procedures are not paid appropriately and are not consistent with OPPS requirements, resulting in patients being forced back into the inpatient hospital setting where the hospital can obtain adequate reimbursement. Briefly, our comments and recommendations are summarized below.

- Payment for orthopedic procedures should be equitable and appropriate to ensure hospitals can financially afford to provide the full range of treatment options to Medicare patients on an outpatient basis.
- Patients should have access to the full spectrum of medically necessary fracture treatment options including external fracture fixation devices. Reimbursement discrepancies limit this access.
- Patient access is dependent upon adequate reimbursement to hospitals for providing services.
- Classification of orthopedic procedures into ambulatory payment classifications (APCs) should be consistent with OPPS requirements.
- APC 46 includes orthopedic procedures that violate the 2-times rule. Costs within this APC range from $11 to almost $20,000.
- As a result of this inappropriate APC classification, Medicare **underpays** for some orthopedic procedures that include the more resource intense and expensive external fracture fixation devices.
- Procedures that involve external fixation devices **always** require additional time, resources and the significant costs of the devices. We have provided CMS with cost data on external fixation devices and CMS should implement measures to distinguish and separate fracture fixation procedures from other alternative procedures as recommended by the APC Panel last year.
- One method is for CMS to create two new APCs with appropriate HCPCS Level II codes for upper and lower extremity fracture fixation devices. Hospitals could report the new HCPCS code when a fracture fixation device is applied and report the CPT code for the procedure. In which case,

- Hospitals would receive payment for both APCs (i.e., the existing APC for the procedure plus the new APC for the fixation device).

- Implementing new APCs and distinct HCPCS codes for upper and lower extremity fixation devices will enable CMS to more appropriately classify orthopedic procedures consistent with the Congressional mandate that APCs reflect clinically similar procedures with similar resources.

I. Patient Access to Appropriate Fracture Fixation Procedures

Treatment with an external fixation device involves surgically attaching screws or pins to the bone above and below the fracture site and connecting these screws or pins to a stabilizer to keep the bones aligned until they are healed. These devices provide real clinical benefits to patients and potential savings to the Medicare program. For example, external fixation devices help promote early mobility. As a consequence, patients may avoid complications associated with prolonged immobilization and disability, providing a more rapid beneficial recovery. In turn, the complications avoided may result in savings to the Medicare program.

Hospitals that furnish external fracture fixation devices so Medicare patients have access to these therapies on an "outpatient" basis should not bear a disproportionate financial burden. Neither should these hospitals encourage physicians to admit patients that need fixation devices as "inpatients" simply to receive adequate reimbursement.

Accordingly, **new APCs are needed to ensure that hospitals receive appropriate and adequate payment for fracture fixation procedures under the APC system.**

II. Orthopedic APC 46 Violates the 2-times Rule

The classifications of orthopedic procedures involving "with and without internal or external fixation" are not clinically similar nor do they utilize similar resources primarily because the CPT code descriptors indicate that the procedures can be performed "with" or "without" fixation devices. As a result, the more resource intense and complex fracture fixation procedures are grouped together with the less complex and less costly cast procedures. For example, upper extremity fixation devices cost about $2,000 and lower extremity fracture fixation devices average between $2,000 to $4,000.

Procedures that involve fracture fixation devices always require additional time, resources, plus the costs of the fixation devices. These procedures must be distinguished from the procedures that do not involve fracture fixation devices.

The table below demonstrates the cost variances among the procedures.

APC	**Cost Ranges within APCs**	Proposed Payment
APC 46	$11 to ~ $20,000	$1,994

Within **APC 46, the cost variance among procedures is almost $20,000**.

Clearly, it is inappropriate to group procedures with such disparate costs together in the same APC.

III. Recommendation -- Create Two New APCs

In 2003, the APC Advisory Panel unanimously recommended that CMS establish a mechanism to ensure appropriate payment for the procedures that include fixation devices. Subsequently, the Alliance met with Cindy Read and representatives from the CMS Division of Outpatient Care. During the meeting, the Alliance made several concrete recommendations to address the issues including:

1. Establish two new APCs with corresponding HCPCS codes for upper and lower fracture fixation devices, or

2. Create two code modifiers (for upper and lower fixation devices) and multiple new APCs.

However, the agency has not taken any action with the exception of indicating its support for new CPT codes.

We wish to emphasize again that the coding and payment issues have been discussed with the AMA CPT Panel and the CPT Panel does not intend on creating over 100 new codes to address a coding and payment issue for the technical component which impacts only hospital outpatient departments.

IV. Ease of Administrative Implementation Supports "Two Codes/Two APCs" Approach

It is clear that the ability to distinguish and separate fracture procedures that involve fixation devices is the crucial first step in calculating and establishing appropriate OPPS payment for the entire series of orthopedic APCs. It is also evident that this is a Medicare APC issue that the agency should address rather than deferring it to the CPT Panel.

As indicated above, the Alliance has made several recommendations to fix the problem: create two new APCs and two new codes or two coding modifiers and multiple new APCs. Either measure would enable CMS to distinguish the more resource-intense fixation procedures from the less costly casting procedures. If a modifier approach is adopted, we expect that many APCs (perhaps different levels for each of the existing APCs) would need to be created to accommodate the variances in costs.

From an administrative perspective, creating two codes and two APCs would appear to be the most sensible because of its simplicity. In addition, we believe that hospital provider compliance and correct coding is more likely to occur if hospitals are required to report one (of two) specific HCPCS code for the relevant fixation device.

Accordingly, we recommend the creation of two new APCs and new HCPCS codes for upper and lower extremity fracture fixation devices. With respect to payment levels for these new APCs, we recommend a payment rate based on average cost of an average configuration as follows:

Gxxx1 Upper extremity fixation →	APC xx1 Upper extremity fixation	$2,000*
Gxxx2 Lower extremity fixation →	APC xx2 Lower extremity fixation	$3,000*

(*estimated average cost)

The Alliance appreciates this opportunity to submit these comments and appreciates the Panel's support for these recommendations.

Respectfully Submitted by Representatives of the Alliance,

Mary Walchak
DePuy, a Johnson & Johnson Company

Keely Scamperle
Orthofix, Inc.

Rhonda Fellows
Orthofix, Inc.

Linda Photopulos
Smith and Nephew

Jim Bechtold
EBI, LP

Eric Rugo
Stryker Corporation

List of CPT Codes Involved and CMS Cost Data For APC 46 Payment $1994.28			
HCPCS/CPT	**Minimum Cost**	**Maximum Cost**	**"True" Median Cost**
21336	817.20	3139.65	1358.14
23515	1159.95	5756.12	2870.66
23532	257.88	2310.33	1284.11
23550	124.55	4238.42	2161.92
23552	1781.01	6094.28	3267.07
23585	1186.95	4817.97	2396.70
23615	705.74	10778.85	2979.65
23616	1003.18	9923.76	6181.65
23630	892.22	5145.00	2471.66
23660	54.63	2594.78	1503.60
23670	431.34	4686.62	2623.26
23680	951.33	7288.99	3386.03
24515	1006.84	7346.91	3217.52
24516	1007.80	17004.55	4047.46
24538	399.41	2359.79	1498.31
24545	860.64	10285.14	3276.62
24546	1824.31	5521.07	3409.66
24566	1159.71	2597.78	1878.75
24575	173.21	19555.11	2470.72
24579	958.27	10275.06	3053.10
24582	1693.68	2560.79	1947.98
24586	1222.56	6045.07	2635.01
24587	2074.56	7468.06	4782.34
24615	1115.61	2631.94	1790.97
24635	1050.08	6588.52	2310.84
24665	677.55	10158.02	2307.77
24666	1492.12	7564.79	4505.65
24685	514.41	6189.17	2104.05
25515	621.66	6083.83	2354.50
25525	2215.99	7994.93	3002.15
25526	2693.81	4960.26	3501.34
25545	892.82	5418.08	2308.78
25574	1822.93	3554.25	2489.32
25575	755.80	8694.62	2334.29
25611	294.69	8319.83	1534.11
25620	472.08	14905.17	2702.84

List of CPT Codes Involved and CMS Cost Data For APC 46 Payment $1994.28			
HCPCS/CPT	**Minimum Cost**	**Maximum Cost**	**"True" Median Cost**
25628	154.71	5695.98	2117.99
25645	731.04	4323.95	1652.67
25651	11.41	1721.67	37.59
25652	1303.28	4167.17	2080.79
25670	2397.20	2910.94	2594.42
25676	3093.93	3093.93	3093.93
25695	1258.49	2448.52	1688.33
26608	285.24	2961.78	1300.68
26615	450.09	4179.65	1764.33
26650	562.96	7754.85	1241.63
26665	598.27	3446.66	1322.82
26676	877.96	1153.24	1015.60
26685	1474.23	2644.87	1828.33
26715	310.33	2804.03	1433.13
26727	322.39	3994.20	1248.88
26735	240.66	4984.59	1665.46
26746	410.52	5158.17	1475.79
26756	419.99	4217.26	1042.73
26765	65.24	5330.51	1375.17
26776	128.42	1888.75	882.44
26785	537.42	1978.36	1085.98
27202	107.22	107.22	107.22
27509	762.34	3909.99	1652.25
27524	673.36	5548.63	2141.58
27566	1093.12	2925.47	2185.60
27615	671.93	2335.54	1270.57
27756	302.03	7513.21	2774.37
27758	1444.05	5888.92	2212.43
27759	1440.20	9290.45	4370.98
27766	893.43	4191.31	2029.53
27784	851.81	2580.24	1606.49
27792	557.23	7295.02	2124.14
27814	521.52	9716.41	2305.04
27822	637.95	5417.54	2659.27
27823	966.91	6719.31	2668.96
27826	1502.11	3234.04	2085.42
27827	1558.77	4955.77	3109.82
27828	1134.14	7428.41	2698.21
27829	588.10	3757.39	1821.66
27846	1567.29	1567.29	1567.29
27848	1788.33	3017.39	2402.86
28406	1008.04	4806.88	1453.18

List of CPT Codes Involved and CMS Cost Data For APC 46 Payment $1994.28			
HCPCS/CPT	**Minimum Cost**	**Maximum Cost**	**"True" Median Cost**
28415	877.88	11982.01	2639.74
28420	4526.91	4526.91	4526.91
28445	1339.34	2888.75	2139.60
28465	669.50	4070.39	1895.93
28476	393.03	3127.34	1446.82
28485	454.45	6277.05	1796.46
28496	739.45	2485.69	1346.16
28505	48.17	3641.39	1328.91
28525	713.06	2838.17	1274.31
28546	423.33	2715.06	1569.20
28576	755.15	755.15	755.15
28585	919.74	2884.44	1902.09
28606	1065.57	1065.57	1065.57
28615	1572.12	4624.76	2859.52
28636	1135.69	3533.79	1333.57
28645	360.68	6881.52	1547.65
28666	950.47	950.47	950.47
28675	593.46	2459.64	1564.48

185

Fresenius HemoCare

A Division of Fresenius Medical Care NA

APC/low CCR's

Bunky Ritter

September 16, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: **CMS-1501-P:** Issues Regarding Claims Billed under CPT Code 36515 and 36516 and Proposed Payment Rate for APC Group 0112 in the 2006 Hospital Outpatient Prospective Payment System Proposed Rule

Dear Dr. McClellan:

Fresenius HemoCare ("Fresenius"), a division of Fresenius Medical Care North America, hereby submits these comments to Proposed Rule CMS-1501-P, "Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" (the "2006 HOPPS Proposed Rule"), published in the *Federal Register* July 25, 2005. Specifically, Fresenius' comments relate to issues regarding claims billed under CPT codes 36515 and 36516 and the proposed payment rate for APC group 0112 by the Centers for Medicare and Medicaid Services ("CMS") in the 2006 HOPPS Proposed Rule.

We would first like to point out that all CPT codes under APC group 0112 are device-dependent procedures and therefore we suggest that APC group 0112 should be included as a device-related APC, included in Table 15 with an adjustment of the median which declined more than 15%. However, the other arguments presented in this comment will demonstrate that even this adjustment will not be sufficient to reflect the real costs and address the inaccuracy of the claims billed under CPT codes 36515 and 36516.

As set forth in further detail below, we believe that in determining the proposed reimbursement for APC 0112, the Agency's payment calculation methodology was flawed and relied on inaccurate and unreliable data. Specifically, the two factors which affect the accuracy and reliability of the claims data upon which CMS relied it its rate setting analysis are:

1. We believe at least 50 percent of claims billed under CPT codes 36515 and 36516 were done so inappropriately.
2. We question whether the majority of claims that were correctly billed under CPT codes 36515 and 36516 included all charge items (i.e. supply costs) and whether they are, therefore, truly representative claims.

Accordingly, Fresenius requests that CMS (1) exclude claims billed under CPT codes 36515 and 36516 from the calculation of the 2006 reimbursement rates for APC 0112 and recalculate the OPPS rate based upon the demonstrably more reliable data provided under CPT 36522, and (2) issue another bulletin clarifying the correct billing procedures for CPT codes 36515 and 36516. Our detailed rationale follows.

CPT Code 36515

Background on PROSORBA® and Apheresis

Fresenius manufactures and distributes the PROSORBA® column, which is a single-use immunoadsorption therapeutic medical device approved by the Food and Drug Administration ("FDA") for the treatment of rheumatoid arthritis ("RA") and idiopathic thrombocytopenic purpura ("ITP"). PROSORBA® is the only protein A column currently approved and available in the United States. The device contains approximately 200 mg of highly purified protein A covalently bound to a silica matrix. Protein A is a component of certain strains of the bacterium Staphylococcus Aureus. The protein A binds to, and selectively adsorbs and removes from the blood, immuno-globulins – commonly called antibodies – and circulating immune complexes – antibodies bound to antigens – that contribute to the symptoms characteristic of rheumatoid arthritis.

RA is a chronic and often debilitating autoimmune disease in which the body's immune system attacks its own tissue, often leading to painful inflammation and deformity of the joints. The disease affects more than approximately 2.5 million Americans, 70% of them women, most between the ages of 25 and 60. It has been estimated that 10% of the 2.5 million RA patients in the United States may benefit from PROSOBRA® column treatment.

Medicare covers the use of protein A columns for the treatment of ITP as well as for the treatment of RA under certain conditions.[1] Payment for claims with dates of service on or after August 1, 2000 is made under the OPPS. Starting in January 2005, payment for these procedures has also been made when they are performed in a physician's office. The ICD-9 codes that support the medical necessity of protein A columns include 287.3 ("primary thrombocytopenia") and 714.0 ("rheumatoid arthritis").

It is our understanding that protein A column treatment is the only approved procedure under CPT code 36515 "extracorporeal immunoadsorption treatment and plasma reinfusion).

Costs of Protein A Column Treatment

The protein A column treatment involves several direct and indirect expenses related to providing the treatment. For purposes of determining reimbursement in the physician office setting, the direct expense categories include clinical labor, medical supplies and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The direct expense categories are well defined by CMS as resource inputs used in

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[1] National Coverage Decision for Apheresis (Therapeutic Pheresis), Pub. 100-3 §110.14.

establishing resource-based practice expense values for the Physician Fee Schedule. *There is no difference in the medical supplies needed to perform protein A column treatment between the hospital outpatient setting and the physician office setting.*

When adding the costs for medical equipment, direct labor and other hospital expenses and overhead charges, the costs associated with a protein A column treatment is substantially in excess of the costs of the related medical supplies alone. Thus, the charges on a claim for a protein A column treatment billed under the HOPPS would be expected to significantly exceed the charges for the medical supplies in all cases. In the 2005 Physician Fee Schedule for CPT code 36515, CMS estimated the medical supply costs for protein A column treatment to be $1,412 and the Relative Value Units to be 68.12. This represents an unadjusted payment rate of $2,581.58 for a protein A column treatment including medical supplies and other expense items based on the 2005 conversion factor of $37.8975.

Claims Analysis – CPT Code 36515

Fresenius engaged The Moran Company ("TMC") to investigate the underlying claims for APC 0112, i.e., CPT codes 36515, 36516 and 36522. In order to analyze the claims used in rate setting, TMC replicated the CMS methodology used to assign original claims as either "singles"— those used in rate setting — or multiples, those not able to be used for rate setting.

TMC first identified all the claims that contained either CPT 36515, 36516, or 36522 and then simulated the CMS rate setting methodology on these CPT codes. The replication of the CMS methodology produced single claim counts and median cost findings within <1% to 6%, which is consistent with TMC's internal validity measures and therefore accurate to warrant further analysis. Table 1 compares the replication to the information published by CMS.

Table 1. Comparison of CMS Published and TMC Replicated Single Count and Median Cost

HCPCS	SI	APC	Payment	CMS "SINGLE" Claim Count	TMC "SINGLE" claim Count	% Difference	CMS Median Cost	TMC Median Cost	% Difference
36515	S	0112	$ 1,590.08	85	84	-1%	$ 1,508.16	$1,508.43	0%
36516	S	0112	$ 1,590.08	554	577	4%	$ 1,321.61	$1,346.26	2%
36522	S	0112	$ 1,590.08	3545	3758	6%	$ 2,095.68	$2,064.31	-1%

TMC identified 86 single claims and 13 multiple claims which contained CPT 36515; 2 claims were then removed during the "trimming" process used to remove outlier cost findings before calculating median cost. CMS was able to use some part of approximately 87% of total claims for rate setting; claims for this procedure were submitted by 29 unique providers, of which 24 unique providers contributed at least one single claim to the rate setting methodology.

As set forth in further detail below, we found evidence that a significant number of claims may have been inappropriately billed under CPT code 36515. For example:

1. Of the 24 providers that billed under CPT code 36515, seven providers (29%) submitted claims which were all at or below $170. This amount would cover only 12% of the costs for medical supplies and far less than that which would reasonably be expected for a complete protein A column procedure. This strongly indicates that the 7 providers billed for something other than a protein A column treatment and thus, a procedure which does not belong to CPT code 36515. Several hospitals listed as submitting claims under 36515 have confirmed that CPT code 36515 is NOT in their system. Some hospitals stated that the claim showed in the CMS database has a charge that would match what is in their system for CPT code 36415, venipuncture, a procedure which historically had a charge appearing under CPT code 36515. The hospitals believe that the numbers were transposed, as they do not find 36515 as either an active or inactive code. Such errors explain the number of claims billed at a very low dollar amounts. However, due to the limited number of total claims, such errors are magnified and can significantly impact the accuracy of claims billed under the respective CPT codes. This makes the calculation of the median questionable.

2. Of the 24 providers that billed under CPT code 36515, 16 providers (67%) have MAXIMUM costs at or below the CMS estimate of $1,412 for medical supplies and far less for the complete procedure. This strongly indicates that the 67% of the providers billed either something other than a protein A column treatment or may not have included charges for medical supplies in the claim.

3. As mentioned previously, Medicare covers the use of protein A columns for the treatment of ITP as well as for the treatment of RA under certain conditions. However, only 43 single claims (51%) were billed with the ICD-9 codes that support the medical necessity of protein A column, specifically 287.3 ("primary thrombocytopenia") and 714.0 ("rheumatoid arthritis"). Thus, nearly half of the claims were for procedures not covered by CPT code 36515.

4. The treatment regimen for protein A columns is 6 treatments per patient for idiopathic thrombocytopenic purpura and 12 treatments per patient for rheumatoid arthritis. Only 8 (33%) of the providers submitted 5 or more claims.

As the manufacturer of PROSORBA ® column, Fresenius Medical Care North America has extensive knowledge of the facilities in the U.S. that are providing protein A column treatments. It is readily apparent to us that a number of providers listed as having submitted claims under CPT code 36515 are not performing protein A column treatments.

Based on our analysis, the evidence above suggests that a significant number of claims billed under CPT code 36515 have been billed either incorrectly or inconsistent with what would reasonably be expected to be billed if the procedure was, in fact, protein A column treatment. The error rate seems to be far beyond what could be considered as acceptable. Thus, we request that CMS exclude claims billed under CPT codes 36515 and 36516 from the calculation of the 2006 reimbursement rates for APC 0112.

CPT Code 36516

Background on LDL-Apheresis

CPT code 36516 is used to report "therapeutic apheresis, with extracorporeal selective adsorption or selective filtration and plasma reinfusion". It is our understanding that this CPT code should be used to report LDL-Apheresis. However, as with the analysis of CPT code 36515, the data suggests that providers are submitting claims under 36516 for procedures other than LDL-Apheresis, and that the data upon which CMS relies does not capture the true costs of providing this procedure. The only approved LDL-Apheresis systems are from B.Braun (H.E.L.P®) and Kaneka (Liposorber®). The ICD-9 codes that support the medical necessity of LDL-Apheresis columns include 272.0 (pure hypercholesterolemia) and possibly 272.2 (mixed hyperlipidemia). Some Local Medical Review Policies (LMRP) only list 272.0 as a covered ICD-9 code for this CPT code. However, our data analysis included ICD-9 code 272.2. Consequently, the amount of correctly billed claims might be overstated.

LDL-Apheresis is indicated for use in performing low density lipoprotein cholesterol (LDL-C) apheresis to acutely remove LDL-C from the plasma of certain high risk patient populations for whom diet has been ineffective and maximum drug therapy has either been ineffective or not tolerated. During LDL-Apheresis, a portion of the patient's blood circulates outside the body. During the procedure, the plasma is separated from the whole blood and the LDL cholesterol is then removed from the plasma. Then, the plasma and blood are recombined and returned back to the patient.

Costs of LDL-Apheresis

LDL-Apheresis involves several direct and indirect expenses related to providing the treatment. For purposes of determining reimbursement in the physician office setting, the direct expense categories include clinical labor, medical supplies and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The direct expense categories are well defined by CMS as resource inputs used in establishing resource-based practice expense values for the Physician Fee Schedule. ***There is no difference between the medical supplies needed to perform LDL-Apheresis in a hospital outpatient setting and the physician office setting.***

When adding the costs for medical equipment, direct labor and other hospital expenses and overhead charges, the costs associated with LDL-Apheresis is substantially in excess of the costs for medical supplies. Thus, the costs of a claim for LDL-Apheresis treatments billed under the HOPPS would be expected to exceed the costs of the medical supplies significantly in all cases. In the 2005 Physician Fee Schedule for CPT code 36516, CMS estimated the medical supply costs for LDL-Apheresis to be $1,485 and the Relative Value Units to be 85.35. This represents

an unadjusted payment rate of $3,234.55 for an LDL-Apheresis including medical supplies and other expense items based on the 2005 conversion factor of $37.8975.

Claims Analysis – CPT Code 36516

TMC identified 577 single claims which contained CPT 36516. Forty-six unique providers contributed at least one single claim to the rate setting methodology.

As set forth in further detail below, we found evidence that a significant number of claims may have been inappropriately billed under CPT code 36516. The following evidence was found:

1. 29 (63%) of the 46 providers have MAXIMUM costs at or below the CMS estimate of $1,485 for medical supplies and far less for the complete procedure. This strongly indicates that 63% of the providers billed either something other than a LDL-Apheresis treatment or may not have included charges for medical supplies on the claim.

2. Only 256 (44%) single claims were billed with the ICD-9 codes that support the medical necessity of LDL-Apheresis (272.0 and 272.2). Thus, more than half of the claims were for procedures which should not be covered by CPT code 36516.

Based on our analysis, the evidence above suggests that a significant number of claims billed under CPT code 36516 have been billed either incorrectly or inconsistent with what would reasonably be expected to be billed if the procedure had, in fact, been LDL-Apheresis. The error rate seems to be far beyond what could be considered acceptable. Thus, we request that CMS disregard ALL claims billed under CPT code 36516 or ensure that the majority of improper or non-representative claims are excluded from CMS' analysis.

Miscoding

There are obviously a significant number of claims being billed under CPT codes 36515 and 36516 which do not belong to any procedure performed under APC group 0112. In addition, there continues to be significant confusion over which CPT code to use for apheresis treatments with the protein A column. Fresenius appreciates CMS's response to its request in January 2005 to remap the previously inappropriate reclassification of CPT code 36515 from APC 0112 to APC 0111. However, despite this correction, if CMS's payment rate data is any indication, providers are still unsure of the correct coding to use for any of the apheresis procedures covered under APC 0112.

Certain Local Coverage Determinations (LCD), both Carrier and Intermediary policies, still instruct physicians and hospitals to use 36516 for Extracorporeal Immunoadsorption (ECI) for RA and ITP using the protein A column. Although the Carrier policies apply only to the professional services of physicians associated with the apheresis procedure, as opposed to the technical component, the policies are still instructive in that they highlight the confusing and

contradictory nature of the instructions that are disseminated to providers regarding billing for the apheresis procedure.

Providers, manufacturers and CMS may all benefit from clear and direct guidance on which specific procedure is properly billable under which specific CPT code. The clinical evidence strongly suggests that protein A column is most accurately billed under 36515, and LDL-Apheresis is most accurately billed under CPT code 36516. Fresenius requests that CMS more clearly define the different categories of apheresis treatments, and instruct providers on proper coding procedures under specific designated CPT codes for each procedure.

Conclusion

The agency's proposed 25.25% reduction in payment rate for APC 0112 in 2006 is excessive. The data and methodology underlying the proposal is fundamentally flawed and clearly not representative of either the actual procedures billed under the CPT codes listed or the true costs associated with the specific procedures covered under APC 0112. Accordingly, such data cannot provide any reasonable basis for setting OPPS rates. Because CMS' analysis relies upon erroneous data, the rates fall below the costs of providing protein A column treatments and LDL-Apheresis. Improper rate setting may, in turn, have a negative impact on Medicare beneficiaries' access to these procedures.

We strongly suggest that CMS reconsider the validity of its data and issue a final rule that constructs reimbursement for APC 0112 as follows. Since the majority of single claims in CMS' analysis were billed under CPT code 36522 ("extracorporeal photopheresis"), CMS should rely only upon these claims to calculate the rate for APC 0112. Eliminating the erroneous data under CPT codes 36515 and 36516 in rate setting will lead to reimbursement for APC 0112 that more closely resembles the actual costs associated with procedures billed under that APC.

In addition, the suggested clarification of correct billing instructions for procedures covered under APC 0112 will ensure that future data analysis will more accurately represent both the procedures that are billed under specified CPT codes as well as the actual costs for performing those procedures. To eliminate the confusion associated with correct billing for apheresis procedures, providers should again be instructed to use CPT code 36515 when billing for protein A column treatments, and CPT code 36516 when billing for LDL-Apheresis treatments. Medicare contractors should be instructed to revise their coverage policies accordingly.

We would appreciate the opportunity to meet with Agency personnel to discuss these comments. If you have any questions, please contact me at 202-296-8632.

Respectfully submitted,

Kathleen T. Smith, RN, BS, CNN
Vice President, Government Affairs

186

September 16, 2005

VIA HAND DELIVERY

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: File Code CMS-1501-P; Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems and Calendar Year 2006 Payment Rates; Proposed Rule

Dear Administrator McClellan:

Novo Nordisk Inc. appreciates the opportunity to submit these comments regarding the Outpatient Prospective Payment System (OPPS) Proposed Rule for Fiscal Year 2006. Novo Nordisk is a healthcare company, a world leader in diabetes care, and the manufacturer of NovoSeven®. The company has the broadest diabetes product portfolio in the industry and a leading position within areas such as hemostasis management. We develop, manufacture, and market pharmaceutical products and services that make a significant difference to patients, the medical profession, and society. NovoSeven® is a recombinant Factor VIIa product that does not replace Factors VIII or IX, but enables coagulation to proceed in their absence. NovoSeven® can therefore be used by people who have developed a resistance to these factors.

Novo Nordisk wishes to comment on proposed payment of hemophilia clotting factors and associated handling costs under OPPS. In 2006, CMS proposes to pay for specified covered outpatient drugs, including hemophilia clotting factors, at 106 percent of average sales price (ASP) updated on a quarterly basis, plus an additional 2 percent of ASP to account for storage, handling, and other administrative costs. CMS also proposes the creation of three Healthcare Common Procedure Coding System (HCPCS) C-codes to track overhead costs for drugs and biologicals.[1]

[1] No payment rates will be associated with these codes. CMS proposes to require hospitals to report the codes beginning in 2006 and to collect hospital charge data based on the codes for 2 years. CMS will consider basing payment for handling fees on the charges reduced to costs beginning in 2008.

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Novo Nordisk supports CMS' proposal to base payment for hemophilia clotting factors on 106 percent of ASP and disagrees with the proposal to pay 2 percent of ASP for clotting factor handling costs. We agree with the proposal to base payment on 106 percent of ASP because this is consistent with payment of other specified covered outpatient drugs paid under OPPS and with payment of hemophilia clotting factors administered in the physician office and hospital inpatient settings of care.

Novo Nordisk urges CMS to reconsider the two percent handling fee with regard to the provision of clotting factors. Both Congress and CMS have recognized that the items and services associated with furnishing clotting factors far exceed the administration costs of other Part B drugs, and therefore have provided a $.14 per unit furnishing fee, updated annually according to the consumer price index (CPI), in the physician office setting of care for the administration of clotting factors.[2] CMS adopted the same payment methodology for clotting factors administered in the hospital inpatient setting in the 2006 Hospital Inpatient Prospective Payment System (IPPS) Final Rule "to ensure consistency in payment for Medicare Part A and Medicare Part B drugs" (CMS-1500-F, p. 47473).

Novo Nordisk urges CMS to apply the same $.14 per unit furnishing fee (updated annually by the CPI)[3] to OPPS payment for hemophilia clotting factors in order to provide adequate reimbursement and to promote consistent payment across all settings of care and payment systems. Hospital outpatient departments purchase clotting factors from the same sources and at the same price as other providers, and incur the same storage, mixing, delivery, and administration costs. The proposed two percent of ASP is not sufficient to cover these costs and would create a payment disparity among the Medicare payment systems. If the proposed OPPS payment methodology were to go into effect, hospitals that provide clotting factors in both the inpatient and outpatient settings of care would receive different payment rates for the same dosage of the same product depending on where the product was administered.

Novo Nordisk also requests that CMS not include blood clotting factors in the collection of overhead cost data using the proposed HCPCS C-codes. Further data collection is unnecessary for this class of drugs because CMS has established a mechanism for calculating and updating the costs associated with administering clotting factors under MPFS and IPPS. Please see the 2005 MPFS Final Rule (CMS-1429-FC, pp. 351-357) for a full discussion of CMS' methodology to calculate and update the furnishing fee.

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[2] Section 303(e)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates the $.14 furnishing fee to account for the mixing and delivery of factors, including special inventory management and storage requirements, ancillary supplies, and patient training necessary for the self-administration of such factors. The provision was implemented in the 2005 Medicare Physician Fee Schedule (MPFS) Final Rule (CMS-1429-FC).

[3] Because the CPI is not yet available for 2006, CMS indicates in the 2006 MPFS Proposed Rule (CMS-1502-P) that the precise handling fee for 2006 will be released in the MPFS Final Rule.

Finally, because clotting factors are not addressed specifically in the 2006 OPPS Proposed Rule, and because coding and payment rules for clotting factors historically have been more complex than rules for other Part B drugs in all settings of care, Novo Nordisk requests that CMS clarify in the preamble and regulatory text of the 2006 OPPS Final Rule all payment provisions related to clotting factors. Specifically, we ask that CMS state explicitly that payment for clotting factors is based on 106 percent of ASP with a $.14 per unit furnishing fee (updated annually by the CPI), and that clotting factors are excluded from the collection of overhead cost data using C-codes. We also ask that CMS clearly state that 1 microgram of NovoSeven® is equal to 1 unit for the purpose of providing the $0.14 per unit furnishing fee in order to prevent the confusion contractors and providers encountered when this policy was implemented under MPFS in 2005.

We appreciate the opportunity to submit these comments on the 2006 Proposed Rule for OPPS and would be happy to answer any questions you may have. Pleae feel free to contact me at (202) 626-4521.

Sincerely,

Michael Mawby
Chief Government Affairs Officer
Novo Nordisk Inc.

187

Imaging
NT APC
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Bundle
Splitting
Rotation

SOCIETY OF
INTERVENTIONAL
RADIOLOGY
Enhanced care through advanced technology
3975 Fair Ridge Drive, Suite 400 North
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September 16, 2005

Via Courier

Mark McClellan, MD, PhD
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Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates [CMS-1501-P]

Dear Administrator McClellan:

The Society of Interventional Radiology (SIR) is a physician association with over 4,000 members that represents the majority of practicing vascular and interventional radiologists in the United States.

SIR appreciates the opportunity to comment upon the proposed rule, Medicare Program; Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and Calendar Year 2006 Payment Rates as published in the July 25, 2005 *Federal Register.*

SIR's comments are directed to:

1. **Multiple Diagnostic Imaging Procedures**
2. **Packaging of Codes**
3. **New Technology APC Assignment**
4. **Vascular Access Procedures**
5. **Inpatient Procedures**
6. **Interrupted Procedures**
7. **Other Issues**

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Multiple Diagnostic Imaging Procedures (Page 42748)

SIR recommends that CMS adopt the one-year delay in implementing the 50 percent discounting rule for multiple diagnostic imaging procedures favored by the APC Panel.

The APC Panel at its meeting in August heard several compelling arguments against CMS' proposed discounting of multiple imaging services (computed tomography, computed tomography angiography, magnetic resonance, magnetic resonance angiography, and ultrasound) of contiguous body sites. SIR shares these concerns. First, CMS purports savings of clerical time, technical preparation, supplies, etc. from multiple imaging services performed at the same session. However, these "savings" account for a small portion of the imaging study's total cost -- making the proposed 50 percent discount excessive. Second, the efficiencies achieved by providing multiple imaging studies may be captured already in the hospitals' annual costs and charges reports. Therefore, it would be inappropriate to apply a discount on already discounted charges. Third, the 50 percent discount has its roots in the Medicare physicians' fee schedule, particularly in the area of physician work associated with multiple surgical procedures. It has not been demonstrated by CMS whether or not such a discounting scheme is appropriate for procedural costs and non-surgical procedures, in particular. For these reasons, the APC Panel voted for a one-year delay in this proposal allowing CMS time to research and collect further information. SIR agrees with the one-year delay.

Proposed Changes to Packaged Services (Page 42691)

SIR maintains that codes 75998 and 76937 should be payable separately under HOPPS.

SIR appreciates CMS' consideration of separate payment for code 76937 (Ultrasound guidance for vascular access), but is disappointed by the decision to continue to package the service. CMS did not explicitly mention code 75998 (Fluoroscopic guidance for vascular access) in the proposed rule, but it too remains packaged inappropriately.

CMS, in its decision to continue packaging code 76937, cites concerns that there may be "unnecessary overuse" of the procedure. In fact, CMS should take the opposite position and encourage the use of imaging guidance. Recommendations from the Stanford Group and the Agency for Healthcare Research and Quality (AHRQ) espouse the advantages of ultrasound guidance of placement of vascular access in improving patient safety and decreasing morbidity. AHRQ cites the lack of payment as a barrier for further adoption of ultrasound guidance. By continuing to bundle payment, CMS is providing a disincentive for a service that should be promoted to Medicare beneficiaries. With regards to CMS' concerns of "overuse", the CPT© descriptor provides such safeguards as interrogation of all potential access sites, documentation of vessel patency, permanent recording of the images, and a report. Overuse is even less for code 75998 which is usually preformed in an angiography room and includes contrast injection and subsequent venography.

In addition to encouraging an important service, separate payment for codes 76937 and 75998 would allow the agency to collect information on prevalence and incidence of imaging guidance. Armed with such data, the agency and other interested parties can engage in a more thoughtful consideration of the issue: (1) is imaging guidance associated more or less with one type of device, (2) site of service (e.g., floor, operating room, angiography suite), (3) patients' risk factors, (4) provider doing the imaging (physician, nurse), to name a few.

A system of separate reimbursement of codes 76937 and 75998 offer several advantages: (1) allows better HOPPS payment granularity when imaging is used and when it is not, (2) provides specificity to the type of imaging modality used and better links payment to the modality, and (3) improves hospital cost accounting.

CMS continues to package the only two codes for reporting renal vein renin sampling (36500 and 75893) and, as a consequence, hospitals are denied payment for providing this important test. SIR recommends that CMS provide for the separate payment for renin sampling under HOPPS.

Renal vein renin sampling is a vital diagnostic test of peptides, which are associated with renal artery stenosis. Renal artery stenosis, in turn, is an important risk factor for cardiovascular morbidity and mortality. The values obtained from the plasma and renal vein renin assay will contribute towards the course of therapy, either medical or endovascular. (For more information on the role of renins play in renovascular hypertension, please see the attached article by Rundback, et al.)

The typical renin sampling scenario is a patient with hypertension and a known renal lesion, based on a previous angiogram, MRA or CTA, of uncertain hemodynamic significance. Renal vein renins are obtained and the patient is discharged home to await the results of the assay. For instance, if renal vein renins are normal, it strongly suggests that the hypertension is not of renovascular origin. Conversely, if the renins are abnormal, this suggests renovascular hypertension. Patients with renovascular hypertension may be managed medically or referred for endovascular intervention.

For over a decade, the only two codes recommended for renin sampling have been 36500 (venous catheterization for selective organ blood sampling) and its associated fluoroscopic/angiographic code 75893. (For coding recommendation, see the attached excerpt from the 2005 Interventional Radiology Coding User's Guide.) From the previous discussion, no other services are provided typically with renin sampling on the same day of service. With codes 36500 and 75893 each having status indicators of "N" (packaged) currently under HOPPS, hospitals are denied payment for their renin samplings. SIR, therefore, recommends that codes 36500 and 75893 be separately payable under HOPPS. We further advise that code 36500 be assigned to APC 103 (Miscellaneous vascular procedures) with a status code of "T" and 75893 placed in APC 0668 (Level I angiography and venography except extremity) with a status code of "S".

Proposed Requirements for Assigning Services to New Technology APCs (Page 42707)

SIR advises against CMS' proposal to require CPT applications for new technologies.

SIR is concerned about CMS' proposed requirement "that an application for a code for a new technology service be submitted to the American Medical Association's (AMA's) CPT Editorial Panel before we accept a New Technology APC application for review." While we appreciate the intent of the proposal, we question whether the CPT Editorial Panel is the appropriate body to conduct reviews of new technology. The CPT Editorial Panel considers physician work. The New Technology APCs, on the other hand, are often device, equipment, drug, etc. specific. Also, there is no consideration of the additional workload this proposal would place on the Editorial Panel and the expected outcomes of this process. Given that the APC Panel has clinical and non-clinical representation, perhaps it or a subcommittee could fulfill the role envisioned by the CPT Editorial Panel in reviewing new technologies.

Vascular Access Procedures (Page 42711)

SIR supports the use of CY 2004 claims data associated with the new vascular access codes introduced in CPT 2004. The proposed three new APCs for vascular access (0621, 0622, and 0623) are a marked improvement over APCs in previous years. We encourage CMS to use subsequent years' data for further refinement of the APCs for vascular access.

In our comments on the 2005 HOPPS proposed and final rules, SIR recommended the use of actual claims data for the new vascular access CPT codes. The new CPT codes represented a significant advancement in both scope and granularity over the previous codes. We were concerned that reliance on historical data related to the cost and utilization of the previous CPT codes would introduce inaccuracies in the APC assignment and weights. SIR views the proposed reconfiguration of the vascular access APCs as a step in the right direction. Since CY 2004 was the first year the new codes were in effect and there may be some "learning curve" issues imbedded in the data, CY 2005 and subsequent years' data may be useful in further refining the APCs.

SIR agrees with CMS' proposal to move code 75940 to an imaging-specific APC.

In prior comments, SIR pointed out that then surgical APC (0187) included imaging services, one such being code 75940 (X-ray placement of vein filter). This introduced a clinical inconsistency. SIR supports the proposed reassignment of code 75940 from APC 0187 to APC 0297.

Inpatient Procedures (Page 42745)

SIR supports CMS' decision to remove TIPS revision (code 37183) from the Inpatient Only List.

SIR is grateful to CMS for considering our previous recommendation to remove TIPS revision (code 37183) from the inpatient only list of services. CMS' decision is appropriate since TIPS revisions are expected to be performed on an outpatient basis.

Interrupted Procedures (Page 42751)

SIR recommends that the definition of "anesthesia" for purposes of HOPPS policy towards payment of interrupted procedures include local anesthesia and conscious sedation.

CMS, in the proposed rule, gave the administration of anesthesia as the threshold when HOPPS would pay fully for an interrupted procedure and when a 50 percent discount is applied. However, the proposed rule is silent on its definition of anesthesia. Clearly, general anesthesia must be included. SIR further recommends that CMS' anesthesia definition extend to local anesthesia and conscious sedation. Hospitals incur costs associated with both of these forms of anesthesia. Additionally, a patient's ability to tolerate local anesthesia and conscious sedation will be a factor in whether the procedure proceeds or is discontinued.

SIR further recommends that HOPPS pay fully for procedures interrupted once the patient has entered the procedural suite (e.g., operating room, angiography suite).

For many minimally-invasive procedures (e.g., endoscopy, endovascular), most of the hospital's consumable medical supplies are committed to the procedure once the patient has entered the procedural room (e.g., endoscopy lab, angiography suite) and before anesthesia (conscious sedation and/or local) is administered. SIR suggests that when a minimally-invasive procedure is interrupted once the patient is in the room, hospitals may report the service with the -74 modifier.

Other Issues

Thrombectomy and Thrombolysis (APC 676)

SIR recommends that CMS revisit the assignment of thrombectomy and thrombolysis procedures under HOPPS.

SIR is concerned that HOPPS payment for thrombectomy and thrombolysis procedures is inappropriately low ($142.42) based on median cost data from one low intensity service. By our estimates, HOPPS payment for thrombectomy and thrombolysis procedures is determined largely on charge data for code 36550 (Thrombolytic declotting of an implanted vascular access device or catheter). Code 36550 usually involves a small injection of a lytic agent, typically by a nurse, to dissolve any thrombus and restore patency to the device or catheter ($143.34 CY2003 median). Thrombectomy and thrombolytic therapies, on the other hand, require a mechanical device costing hundreds of dollars or significant quantities of expensive lytic agents, respectively. Adding to this problem is the fact that thrombolytic therapy is rarely reported as a single-code claim and thus there are few available claims for APC weight calculations.

New percutaneous thrombectomy codes will be implemented next year. Unfortunately, a year or so may pass until CMS has actual claims data on which to reconfigure the APCs. In the meantime, SIR encourages CMS to use any thrombectomy device related data, either from C-codes or external sources, for APC purposes. SIR offers its assistance to the agency to refine these APCs.

***

SIR appreciates the opportunity to comment on the proposed rule for the 2006 Medicare hospital outpatient prospective payment system (HOPPS). If you have any questions or require additional information, please contact Michael R. Mabry, Assistant Executive Director at (703) 460-5561 or mabry@sirweb.org.

Sincerely,

Michael E. Edwards, MD
Councilor, Health Policy & Economics

cc: Ken Simon, MD, CMS
Edith Hambrick, MD, CMS
Rebecca Kane, CMS
Peter B. Lauer, CAE, SIR

Attachments: (1) John H. Rundback, Timothy P. Murphy, Christopher Cooper, and Joshua L. Weintraub Chronic Renal Ischemia: Pathophysiologic Mechanisms of Cardiovascular and Renal Disease J Vasc Interv Radiol 2002 13: 1085-1092.
(2) Excerpt from 2005 Interventional Radiology Coding User's Guide regarding recommended coding of renin sampling.

Review Article

Chronic Renal Ischemia: Pathophysiologic Mechanisms of Cardiovascular and Renal Disease

John H. Rundback, MD, Timothy P. Murphy, MD, Christopher Cooper, MD, and Joshua L. Weintraub, MD

Chronic renal ischemia caused by renal artery stenosis (RAS) elicits a complex biologic response. Although the traditional pathophysiologic pathways underlying renal ischemia have been well studied, there is emerging evidence that additional mechanisms may be responsible for producing many of the hemodynamic alterations and end-organ injury seen in patients with RAS, including persistent hypertension, renal insufficiency, and cardiac disturbance syndromes. A better understanding of these mechanisms may allow earlier identification of RAS, provide markers to predict the response to revascularization, or allow unique therapeutic targets for drug development. This and a subsequent article will explore the pathophysiologic and clinical implications of chronic renal ischemia.

Index terms: Hypertension, renovascular • Kidney, blood supply • Renal arteries, stenosis or obstruction

J Vasc Interv Radiol 2002; 13:1085–1092

Abbreviations: AA = arachidonic acid, ACE = angiotensin converting enzyme, AT = angiotensin, NO = nitric oxide, RAH = renal artery hypertension, RAS = renal artery stenosis, SMC = smooth muscle cell

RENAL artery hypertension (RAH) caused by atherosclerotic renal artery stenosis (RAS) is the most common cause of secondary hypertension and is an increasingly recognized precursor to chronic renal insufficiency (1–3). Although rare in the general population, certain clinical characteristics increase the likelihood of identifying RAS, including age older than 50 years, duration of hypertension shorter than 1 year, accelerated hypertension, history of cerebrovascular, coronary artery, or peripheral vascular disease, hypertensive retinopathy, abdominal or flank bruit, chronic renal failure, and type-2 diabetes (4).

In patients with chronic renal dysfunction and end-stage renal disease, RAS is present in 14%–22% of individuals (5–9), although often unrecognized (2,5). More importantly, there is emerging evidence that RAS may be an important risk factor for cardiovascular morbidity and mortality (10–13). Despite the availability of highly effective antihypertensive agents and the ability to anatomically correct most cases of RAS with percutaneous transluminal renal angioplasty or endoluminal stent placement, the clinical response to treatment remains variable. Clearly, more understanding of the complex physiologic alterations inherent to the disease process is needed to improve patient selection for revascularization as well as to identify novel therapeutic targets to prevent disease progression. This article will explore fundamental and evolving concepts underlying the hemodynamic and biochemical consequences of renal ischemia. In a subsequent article, we will then review the evidence implicating chronic renal ischemia as an important cause of increased risk for myocardial infarction, stroke, heart failure, and renal failure beyond the degree explained by blood pressure elevation alone.

PATHOPHYSIOLOGY OF RENAL ISCHEMIA: FUNDAMENTAL CONCEPTS

Acute Renal Artery Stenosis and Two-kidney, One-clip Hypertension

The kidneys normally receive approximately one quarter of the cardiac output. Under normal physiologic conditions, fluid and electrolyte homeostasis is maintained by alternations in renal perfusion and glomerular filtration. Autoregulation of renal blood flow is modulated predominantly by prostaglandin- and angiotensin (AT) II-induced changes in renovascular resistance, mediated predominantly via an effect on calcium channel–regulated vasomotor tone of the preglomerular (afferent) arteriole. As a result, glomerular filtration pressure is maintained over a wide range of systemic arterial pressures.

The early biochemical abnormalities that occur after experimental clip-

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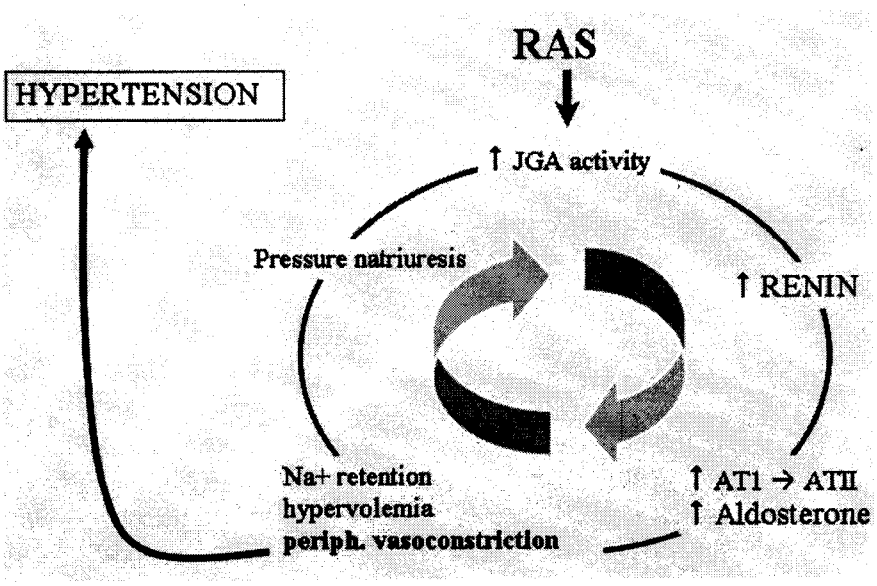

Figure 1. Two-kidney, one-clip model of renovascular hypertension. JGA = juxtaglomerular apparatus; AT1 = angiotensin I; ATII = angiotensin II.

ping of the renal artery in dogs were first described by Goldblatt and coworkers in 1934 (14) (**Fig 1**). The sequence of pathophysiologic events in RAH can be divided into three phases (15). In the first phase, ie, that seen with acute unilateral RAS (Goldblatt two-kidney, one-clip model), a reduction in renal blood flow below a critical perfusion pressure of 70–80 mm Hg activates stretch-sensitive receptors within the juxtaglomerular apparatus and sensors of sodium delivery to the macula densa (16,17). These receptors then stimulate the constitutive release of renin by the juxtaglomerular cells of the afferent arteriole (18–20).

Renin catalyzes the cleavage of angiotensinogen to AT I, which is subsequently converted in the lung and periphery to the active form ATII by the dipeptidyl carboxypeptidase angiotensin converting enzyme (ACE) (21). ATII is one of the most potent vasoconstrictors known, being five times more potent than epinephrine (22). ATII-provoked peripheral vasoconstriction is mediated via binding to protein-specific membrane-bound peripheral smooth muscle receptors (23). This in turn activates a cascade of intracellular signaling events, resulting in stimulation of the intracellular phosphoinositide-Ca^{2+}-protein kinase C effector system. Rapid smooth muscle cell (SMC) contraction then occurs as a result of liberation of intracellular Ca^{2+} stores under the effect of inositol triphosphate (24).

ATII stimulation of AT_1 receptors in the adrenal cortex also promotes the conversion of corticosterone to aldosterone. This mineralocorticoid then acts to increase the reabsorption of Na+ and water by the distal tubule of the kidney. In phase-I RAH, expansion of plasma solutes and volume is blunted by increased Na+ excretion by the normally perfused contralateral kidney, a process called pressure natriuresis (25). As a result, renin and angiotensin levels remain elevated and acute increases in blood pressure are predominantly determined by the peripheral vasoconstrictive effects of ATII (26–28). In this phase, renal revascularization would be expected to reverse the consequences of hyperreninemia and normalize blood pressure, an assertion supported by the observation that the hypertensive response to ATII inhibitors is strongly predictive of the outcome after revascularization (29).

It should be noted that the production of renin is also prostaglandin-mediated and may be partially muted by the administration of prostaglandin inhibitors such as aspirin and indomethacin (30). The renin response to prostaglandins may vary with the severity of the RAS of the affected kidney (31). Imanishi and colleagues (31) showed that prostaglandin E2 promotes renin production in patients with moderate RAS whereas prostaglandins E2 and I2 contributed in cases of severe RAS.

Pressure Natriuresis and Maintenance of Isovolemia in Acute Two-kidney, One-clip Hypertension

In Goldblatt two-kidney, one-clip RAH, hypertension causes increased renal perfusion pressure to the contralateral kidney. Subsequent myogenic and tubuloglomerular feedback mechanisms result in autoregulatory changes, including an increase in renal medullary blood flow and decreased reabsorption of sodium by the renal tubules. Increased renal medullary blood flow has been observed to produce parallel increases in the renal interstitial hydrostatic pressure, mediated in part by ATII and prostaglandins (1), thereby potentially eliminating the normal osmotic gradient along the tubule and promoting diuresis. High intrarenal concentrations of AT type 1 (AT_1) receptors have been detected in the proximal and distal tubules and mesangial cells of animals with RAS (31). These findings corroborate that ATII is strongly involved in paracrine regulation of renal function, including renal blood flow, and fractional sodium excretion (32). Although ATII predominantly affects the efferent arterioles to preserve glomerular filtration, some ATII-induced constriction of the afferent arterioles also occurs. This is offset by the vasodilatory effects of prostaglandins, particularly prostaglandin E_2, which preferentially act on the preglomerular vessels (33,34). Nitric oxide (NO) also appears to be important in modulating medullary renal tubular and vascular function with consequential effects on fluid and electrolyte homeostasis (35).

Physiologic Disturbances in Chronic Renal Ischemia

Pathophysiologic changes in chronic RAH occur with bilateral RAS (Goldblatt two-kidney, two-clip model), stenosis to a solitary kidney, or unilateral stenosis with contralateral nephrosclerosis (36). In these conditions, renin and ATII levels gradually

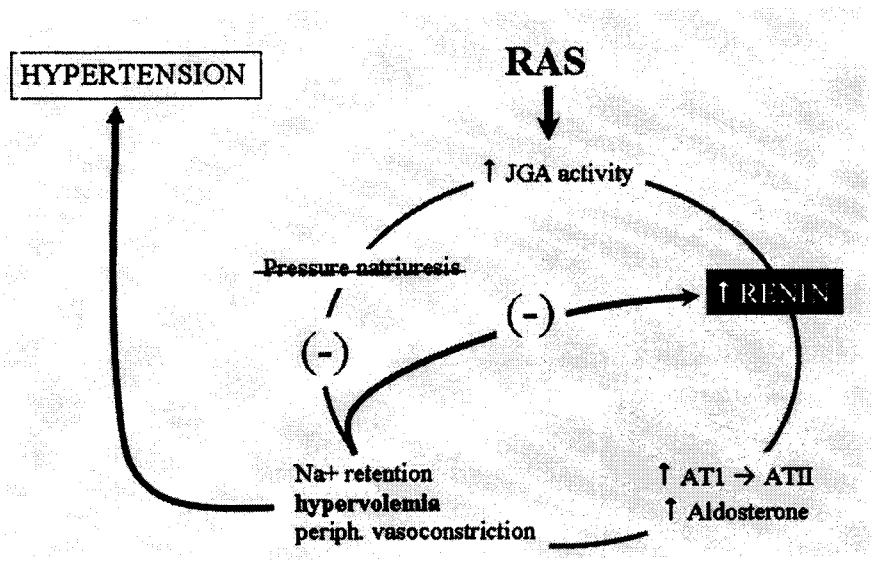

Figure 2. Two-kidney, two-clip model of renovascular hypertension. JGA = juxtaglomerular apparatus; AT = angiotensin.

decrease and the resulting phase-II RAH is characterized by normal or near-normal levels of renin and ATII. This decrease in renin production is partly modulated by volume expansion with normalization of perfusion pressure to the ischemic kidney, an effect that can be offset somewhat by salt restriction or the presence of a sufficiently severe RAS to prevent perfusion pressure beyond the RAS (1). However, the predominant cause of renin decrease is feedback ATII suppression of renin mRNA expression (37). In the two-kidney, two-clip model, global renal dysfunction precludes pressure natriuresis. Consequently, persistent increases in blood pressure are independent of the peripheral vascular effects of ATII and promoted through Na+ retention and expanded blood volume (38) (**Fig 2**). This ATII independence has also been demonstrated in chronic-phase two-kidney, one-clip rat models by a reduced depressor response to renal unclipping in animals with hypertension refractory to the AT_1 receptor antagonist losartan (28). Interestingly, although peripheral ATII levels are not elevated, persistent intrarenal ATII augmentation occurs despite systemic renin depletion, implying a separate mechanism for renal ATII regulation than a renin-dependent mechanism (39). Existing evidence suggests that the preserved renal vascular response to reduced circulatory levels of ATII is a result of upregulation of the number and quality of the intrarenal AT_1 receptors, which may also help to prevent intrarenal ATII degradation (40).

Despite low peripheral ATII levels, the gradual development of hypertension in two-kidney, two-clip animal models may still be stimulated by ATII. In this regard, sodium retention has been shown to amplify vascular reactivity to low levels of ATII, perhaps as a result of upregulation of peripheral vascular AT_1 receptor mRNA and receptor density, thereby sustaining hypertension (1,40). In addition, a slow-pressor response has been described as a result of cardiovascular amplification occurring as a result of hypertrophy of the left ventricle and peripheral arteries (25). As will be discussed, other pathways including lipooxygenation and sympathetic activation further contribute to this slow-pressor response.

Although revascularization of the underlying RAS in phase-II RAH may improve blood pressure, the outcome is variable and largely determined by the degree of intrinsic renal abnormalities. If renal ischemia persists, phase-III RAH ensues, in which extensive destruction and atrophy of the renal parenchyma caused by global ischemia and nephrosclerosis results in irreversible renal failure and hypertension that is not correctable by renal revascularization (15).

CHRONIC RENAL INSUFFICIENCY

Clinically, phase-II and phase-III RAH correlate with the clinical syndrome of ischemic nephropathy (15). Although patients with ischemic neuropathy frequently have hypertension, this syndrome is dominated by progressive excretory dysfunction caused by global renal hypoperfusion (41). Chronic renal insufficiency often accompanies RAS, and the risk of progression to renal replacement therapy for those with chronic renal insufficiency is significant, particularly when RAS is present bilaterally (42). The risk of chronic renal insufficiency is determined in two-kidney, one-clip models of hypertension by the extent of underlying hypertensive or hyperfiltration parenchymal injury in the nonstenotic kidney (43) and in two-kidney, two-clip models by the severity of global glomerular sclerosis and tubular dysfunction. Such progressive loss of renal parenchyma occurs in part as the result of cumulative and repeated ischemic insults with concomitant localized cellular damage, disruption of tubular membrane polarity (44), and cytoskeletal changes affecting cellular ion gradients and cellular recovery (45). Renal damage may also occur as a result of the repeated downstream effects of cholesterol crystals and cytokines liberated at the site of the proximal atherosclerotic plaque, a process termed "atherosclerotic nephropathy" by Scoble (46) and validated by other investigators (47). Renin itself may also have a direct renal vasculotoxic effect (48), and ATII has been shown to augment progressive tubulointerstitial injury in chronically ischemic but not normal kidneys (49), an effect partially blocked by selective AT_1 receptor antagonists.

Most research has described a central role of the renin–AT system in ischemic nephropathy. Decreased blood flow to the kidney increases renin production by juxtaglomerular cells and renin increases the production of ATII. The paracrine activity of ATII induces efferent arteriolar constriction, which in turn aids in maintenance of the glomerular filtration rate. In 1983, Hricik et al (50) described

renal failure secondary to ACE inhibition in the setting of bilateral renal artery stenosis. In Goldblatt's two-kidney, one-clip models, ACE inhibition resulted in decreased glomerular filtration rate and increased tubular atrophy. The decrease in glomerular filtration rate could not be solely attributed to hypoperfusion secondary to decreased systemic pressures (51). It has been proposed that reversal of the angiotensin-mediated efferent arteriolar vasoconstriction by ACE inhibition decreases glomerular filtration pressure and thereby glomerular filtration rate. However, only a small subset (6%–38%) of patients with ischemic renal disease present with acute renal dysfunction (52).

Several new observations have added to our understanding of ischemic nephropathy. First, chronic hypoperfusion caused by stenosis is usually accompanied by renal atrophy. This occurs even though normal kidneys remain viable with blood flows and pressures below those required for glomerular filtration (53), because less than 10% of oxygen delivery is required for kidney tissue metabolism. Therefore, chronic ischemia does not damage renal tissue simply by lack of oxygen delivery (54).

Gobe et al (55) studied the cellular events related to unilateral renal artery stenosis in the rat model. The ischemic kidney underwent progressive atrophy with compensatory weight gain of the contralateral kidney. During the initial phase (2–5 d), tubular cell death resulted from necrosis and apoptosis, whereas nuclear thymidine uptake showed increased labeling and mitosis, providing evidence of epithelial repair. During the chronic phase (10–20 d), renal atrophy progressed and cell death resulted from apoptosis alone.

After reversal of RAS or nephrectomy of the nonstenotic hypertrophied kidney, evidence of regeneration consisting of hypertrophy and hyperplasia was found. Gobe et al (55) hypothesized that the stenotic kidney is deprived of what is sometimes referred to as "renotropin," a factor inducing compensatory renal growth as well as renal regeneration and regrowth. These findings imply that, rather than leading to passive shrinkage of the kidney, chronic ischemia is a dynamic process comprising not only an adaptation to reduced blood flow but also a vigorous potential for tubular cell regeneration. Therefore, tubular cell regeneration may be a factor involved in the improvement of renal function often observed after revascularization.

Ischemia is considered by some authors as the first of many fibrogenic signals that set off a cascade of cellular and molecular responses eliciting extracellular matrix buildup and subsequent renal atrophy (56). ATII increases the expression of the transforming growth factor-β gene (57) and interstitial platelet-derived growth factor-β chain mRNA (58), both of which are associated with fibrosis by increasing the extracellular matrix in the interstitium (59). A host of experimental data suggest that ACE inhibitors limit interstitial fibrosis and function by functioning as antifibrotic as well as antihypertensive agents (60).

Vasoactive Molecules Involved in RAH

Vasoconstrictors
Angiotensin II
Endothelin
Thromboxane
Noradrenaline
Vasodilators
Nitric oxide
Prostacyclin (PGI_2)
Kallikrein
Growth factors
Insulin-like growth factor
Transforming growth factor β
Natriuretic peptides
Brain natriuretic peptide
Atrial natriuretic peptide
Ventricular natriuretic peptide
Adrenomedullin
Proximally liberated substances
Cholesterol emboli
Oxygen free radicals
Oxidized low-density lipoprotein

EMERGING CONCEPTS IN RENOVASCULAR PATHOPHYSIOLOGY

Suppressing ATII in experimental RAS delays but does not prevent the onset of hypertension, implicating etiologic factors other than renin–AT and aldosterone (29,61,62). There is evolving evidence that other mechanisms contribute to this process, including the liberation of vasoactive substances, sympathetic activation, and oxidative stress.

The Role of Vasoactive Cytokines

Numerous vasoactive substances are elicited or activated in experimental RAS, producing a complex pattern of deleterious and protective biologic responses that affect cardiovascular disease. Compounds implicated in the pathogenesis of RAH are shown in the **Table**. Although a complete understanding of the role of each of these compounds is lacking, the molecular effects of several substances have been elucidated.

In two-kidney, one-clip rat models of RAS, vascular shear stresses induce the renal synthesis of NO by the ischemic kidney. NO activity is implicated in altering medullary blood flow, thereby affecting pressure natriuresis (35). NO also increases ipsilateral and contralateral renal perfusion and attenuates the blood pressure elevation after renal artery clipping (63,64). NO also protects against vascular and myocardial fibrosis; ATII-induced suppression of NO expression in experimental and human RAS produces cardiac remodeling and vascular endothelial dysfunction (65,66).

Endothelin levels are increased in association with systemic atherosclerosis (67), but a specific relationship between plasma endothelin and RAS is uncertain (68,69). Endothelin causes vascular SMC contraction and hypertension through the protein kinase C effector system and has been implicated as a mediator of cardiac hypertrophy independent of blood pressure control (70). This latter effect is probably caused by modulation of cardiac and brain natriuretic peptide gene expression, an effect demonstrated in animal studies (71). Hypertensive rats exposed to endothelin antagonists have a blunted pressor response to renal artery clipping, reduced left ventricular hypertrophy, and a lower incidence of stroke and renal injury (71,72)

Other vasoactive molecules may also be involved in mediating vascular, renal, and cardiac damage in patients with chronic renal ischemia. Insulin-like growth factor has been identified as a stimulus for ventricular thickening and stiffening (73–76). Adrenomedullin, a vasodilator and natriuretic peptide found in elevated levels in animal models of Goldblatt hyper-

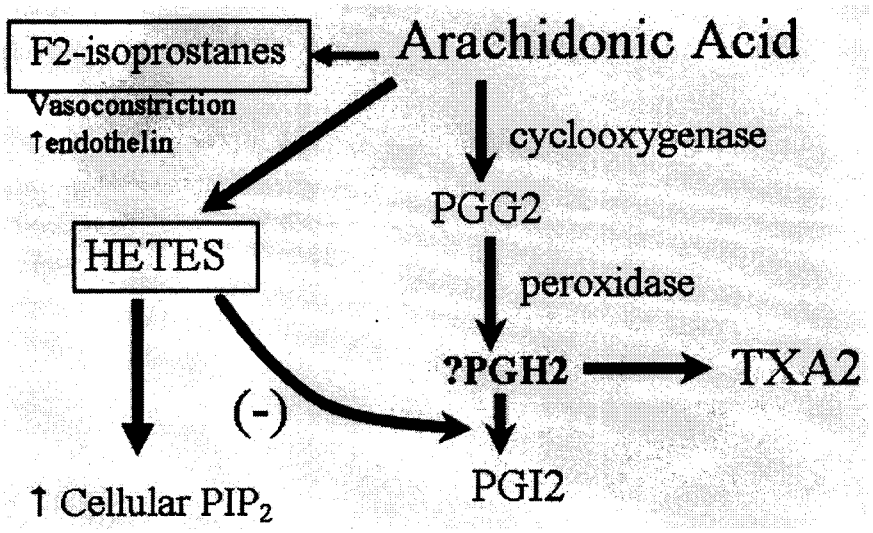

Figure 3. Effect of lipooxygenase products on chronic hypertension. HETES = hydroxyeicosatetraenoic acids; DAG = diacyl glycerol; PIP_2 = phosphatidylinositol biphosphonate; PH = prostaglandin; TXA2 = thromboxane; PG = prostaglandin; PGI2 = prostacyclin.

tension, may have beneficial effects in preventing renal and cardiac disease progression (77).

Sympathetic Activation in Chronic Renal Ischemia

Arterial noradrenaline levels are increased in patients with RAS compared to healthy controls, implicating β-adrenergic stimulation of renin release and peripheral vasoconstriction (78,79). The role of the sympathetic nervous system has been confirmed by the results of a recent study (79) that measured sympathetic nerve activity in patients with renovascular hypertension. In these patients, muscle sympathetic nerve activity and total body norepinephrine spillover increased 60% and 100%, respectively, compared to normal controls (79). Rauch and Campbell (80) have suggested that alterations in catecholaminergic tone in the mid-medulla are involved in the increase of arterial pressure in the two-kidney, one-clip model. This observation has been supported by the observations that (i) animal models of renovascular hypertension have increased plasma catecholamines, (ii) catecholamine inhibition decreases blood pressure, (iii) plasma catecholamine levels decrease after the ischemic kidney is unclipped, and (iv) blood pressure decreases after denervation of the clipped kidney (80). However, more recent research suggests that chronic human renovascular hypertension involves synergistic stimulation of renin–AT and sympathetic nervous systems (81,82).

Oxidative Stress, Reperfusion, and Free Radical Injury in Renovascular Disease

Normally, essential fatty acids and membrane phospholipids are converted to arachidonic acid (AA), a precursor of prostaglandin synthesis. Several potential metabolic pathways for AA exist. In a healthy state, cyclooxygenation of AA produces prostaglandin G_2, a precursor to prostacyclin and thromboxane, which are produced in proportions to maintain peripheral vascular homeostasis (83). Under conditions of physiologic "oxidative" stress including chronic renal ischemia, alternative metabolic pathways dominate (**Fig 3**), including the lipooxygenation of AA to vasoactive leukotrienes and other important molecular bioregulators including hydroxyeicosatetraenoic acids (1).

In patients with chronic renal ischemia, emerging evidence suggests that a *sustained* pressor effect may be caused by peripheral smooth muscle contraction stimulated by lipoxygenase products (1). Hydroxyeicosatetraenoic acids depolarize the surface membranes of vascular SMCs and activate intracellular signaling (84). In this process, phospholipase conversion of phosphatidylinositol diphosphonate results in the production of diacylglycerol, a cellular intermediary and stimulant of the protein kinase C effector system. This results in a Ca^{2+} influx from the interstitial space, resulting in SMC contraction (1). The potential role of lipoxygenase activation in RAH has been demonstrated in animal models, in which the experimental administration of diacylglycerol inhibitors attenuates ATII release and aldosterone secretion (81) and direct antagonism of 12-lipoxygenase prevents SMC hypertrophy (85).

In addition to its direct vasoconstrictive properties, hydroxyeicosatetraenoic acids may interfere with the normal cyclooxygenation of AA, preventing the production of the vasodilator prostacyclin, PGI_2 (1), and instead producing thromboxane A2, a potent vasoconstrictor and platelet aggregator (**Fig 3**).

Other oxidative pathways also appear to affect endothelial and vascular SMC function. Sustained low levels of ATII have been associated with the production of reactive oxygen species including superoxide (86), yielding the strong oxidant peroxynitrite (87). Peroxynitrite oxidation of AA releases F2 isoprostane species, which are potent vasoconstrictors and antinatriuretic substances. Moreover, F2 isoprostanes may induce the release of endothelin from vascular SMCs, thereby further augmenting vascular SMC contraction and augmenting vascular and cardiac hypertrophy (87,88). In a recent study of 15 patients with renovascular hypertension and 15 controls, patients with RAS had decreased peripheral blood flow and increased serum and urinary markers of oxidative stress, all of which normalized after renal artery angioplasty (89).

Oxidation-sensitive mechanisms may also produce direct renal injury. Kidneys affected with chronic renal ischemia have diminished levels of endogenous oxygen free radical scavengers and an impaired ability for cellular repair. Superoxide and peroxynitrite generation fosters mesangial damage and interstitial fibrosis, a mechanism important in other forms of renal dis-

ease (88). The exact role of these processes in RAH is still to be determined.

CONCLUSIONS

Epidemiologic and experimental evidence points to the activation of the AT–aldosterone system and other pathways as important in increasing the risk of cardiovascular events (88,90–92). The pathophysiologic changes induced in RAH have deleterious effects greater than those caused by blood pressure elevation alone, including promoting proliferation of SMCs, rupture of atherosclerotic plaques, vascular endothelial dysfunction, left ventricular hypertrophy, and inhibition of fibrinolysis (88,91). Chronic renal insufficiency is also a common and detrimental sequela of RAS. For these reasons, the resulting risk of cardiovascular mortality in patients with RAH is increased more than three fold compared with the normal population (11,78).

A better understanding of the pathophysiologic mechanisms of chronic renal ischemia has several implications. First, it is plausible or even likely that control of blood pressure alone with antihypertensive medications may not be sufficient to prevent end organ damage, and ultimately clinical events. Additionally, identification of new molecular targets responsible for sustained hypertension and cardiovascular and renal damage may guide the development of new therapeutic agents. The recognition of reliable biochemical markers indicative of an activated pathophysiologic state in association with RAS may have important prognostic significance and may someday lead to patient-specific neurohumoral modification therapy. Finally, it is hoped that at least some of these markers may help predict outcomes after revascularization to allow better selection of patients suitable for renal angioplasty and stent placement.

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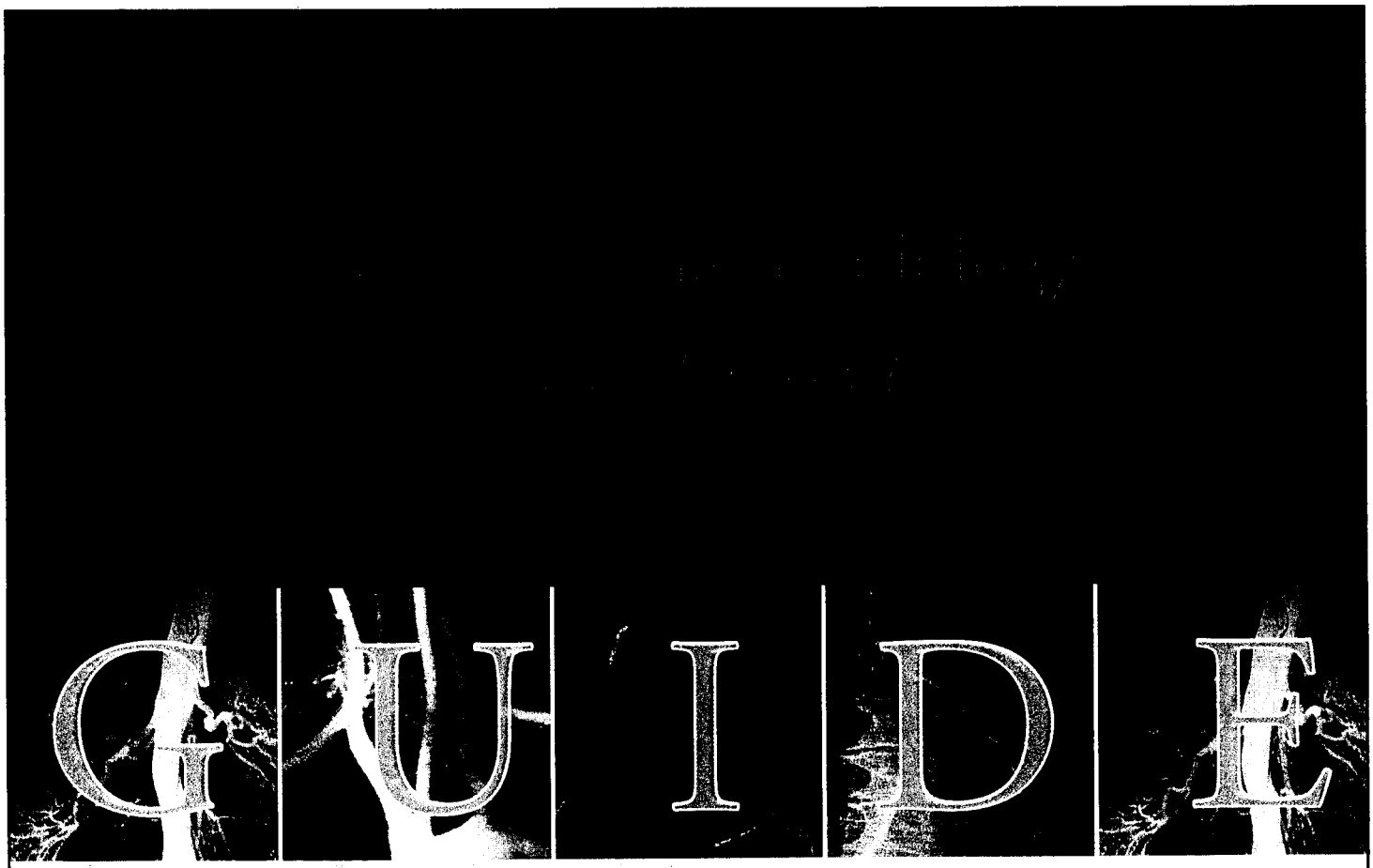

eleventh edition

2005

Coding Examples Answers, Venous

V1. Inferior vena cavagram and inferior vena caval filter placement.

37620, 36010, 75825-59*, 75940
Access into inferior vena cava is coded 36010. The performance of a full and complete IVC gram is coded 75825. Filter placement is coded 37620. The corresponding RS&I code for filter placement is 75940. (Both the filter and the inferior vena cavagram RS&I codes are reported when a full IVCgram is performed.) *Modifier "-59" must be appended to diagnostic venography when reported in conjunction with a therapeutic RS&I code on the same date of service.

V2. Bilateral main renal vein renin samples with venography and peripheral sampling.

36500-50, 75893 X 2
The NCCI edits exclude billing for a selective venous catheterization access code when using 36500. Therefore, 36011 should no longer be billed for selective renins, with or without venography. The procedural code for renal vein renin sampling (36500) should be used for each organ selected, but is not used for nonselective sampling from the IVC. The RS&I code for venous sampling (75893) is likewise used for each selective organ sampled and includes venography. Multiple samples from within the same organ would be coded only once.

V3. SVC gram through port or tunneled catheter.

75827
Code 36005 is no longer applicable for injection into central veins through an existing catheter or IV. The CPT descriptor language for this code was revised in *CPT 2002* to read "Injection procedure for extremity venography". To report venography of the SVC, use the RS&I code 75827. Code 75825 is used to report venography for IVC catheter and code 75820 is applicable for venography when the catheter tip is in a peripheral or central vein short of the cava.

If less than a complete SVC gram is performed, see code 76000. Additionally, E&M services supported by appropriate documentation reflecting the level of decision-making performed may be reportable.

A new code for radiological evaluation of a venous access device is anticipated to be available in 2006.

188

BBP
NPT OBR
ODrugs

Baxter

September 16, 2005

BY HAND DELIVERY

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Attention: CMS-1427-P
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

SUBJECT: CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates) – Non Pass-Throughs; Orphan Drugs; Vaccines; and Drug Administration

Dear Administrator McClellan,

Baxter Healthcare Corporation (Baxter) appreciates the opportunity to comment on the above-mentioned proposed rule published in the Federal Register on July 25, 2005 (the "Proposed Rule").

Baxter would like to thank you and the Secretary for your willingness to work with patients, providers, manufacturers and suppliers of health care products to arrive at adequate payment for providers who serve Medicare beneficiaries. Appropriate reimbursement continues to a be a key factor in ensuring patient access to treatment, especially when patients are prescribed high-value and/or recurring treatment in a hospital outpatient department or emergency room. With these critical patient access issues in mind, we address specific concerns related to the payment policies set forth in the Proposed Rule.

Our comments focus on the plasma-derived therapies marketed by the BioScience division of Baxter. The plasma-derived therapies discussed in these comments treat rare disorders such as primary immune deficiency, alpha$_1$-antitrypsin deficiency and idiopathic thrombocytopenia purpura (ITP). In particular, Baxter is extremely concerned that the proposed revision in the reimbursement formula will result in a payment rate that is below the cost at which hospital outpatient departments can acquire Intravenous Immune Globulin (IVIG), Alpha-1 Proteinase Inhibitor (A1PI) and Rh$_o$(D) Immune Globulin Intravenous

As you may be aware, plasma-derived therapies have unique inherent manufacturing costs not found in other pharmaceutical products covered by the Medicare program. Human plasma, the "raw ingredient" of all such therapies, is costly, as well as labor and time intensive to collect and process. Production of plasma-derived therapies includes numerous steps that begin with donor recruitment, health screening, plasma collection and extensive serum testing. The donor plasma is then pooled into "lots" and held in inventory for a minimum of 60-days. If any problems are identified during this period from sequential PCR viral screenings, the entire lot of pooled plasma is rejected and definitive steps are taken to identify and defer the problem donor from future donations. Targeted proteins, effective in treating various medical conditions, are then separated from the plasma and subjected to multiple viral removal and/or inactivation steps. The entire production process, from plasma donation to a finished therapeutic takes approximately seven months to complete.

While each of the therapies discussed in these comments has unique circumstances that raise access concerns, they also have a shared barrier to adequate and truly cost-based reimbursement. All of these products are impacted in varying degrees by the use of reimbursement codes that include more than one biological product. The codes represent therapies of differing characteristics and value. The bundling of plasma-derived therapies is of particular concern in 2006 because of the proposed movement to an average selling price (ASP) based system. As CMS is aware, there are circumstances in which a weighted ASP does not reflect the current hospital acquisition cost. Codes that contain multiple therapies are particularly vulnerable. We are hopeful that CMS will continue to recognize the importance of providing access to all therapies so physicians may provide beneficiaries the most medically appropriate treatment available.

with you and the staff at CMS toward that goal. If you would like further information please contact Meredith Zerbe at 703-237-7940 or me at the address below.

Sincerely,

Senior Director
Healthcare Economics
Baxter BioScience, North America
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